change from the fourth quarter of '06 on the same product? So stripping mix out, what was the pure price difference between the two?

Mike Baker - ArthroCare - President and CEO - It is actually more mix than it is price increases. It is pretty tough to get price increases in this environment. But we are seeing a mix shift. It is driven by the fact that our highest-margin products are also our fastest-growing products . . . So we - we are seeing the mix of our sales shift more than anything else.

*Mark Mullikin - Piper Jaffray - Analyst -* So when you say in the press release the average selling price improved, there is - you are talking about mix as well?

Mike Baker - ArthroCare - President and CEO - Yes.

Mark Mullikin - Piper Jaffray - Analyst - Is that correct.

Mike Baker - ArthroCare - President and CEO - It really is much more mix than it is - the prices of individual products haven't changed that much.

170. Defendant Baker addressed additional questions regarding average selling prices, volume of sales and the average selling prices of DiscoCare inventory:

*Bill Plovanic - Canaccord Adams - Analyst -* Okay. Just to jump on to Mark's question, in terms of, you know, mix, ASP versus volume. If you look at volume on disposables year-over-year, what type of growth rate are you seeing on that relative to the overall reported numbers?

*Mike Baker - ArthroCare - President and CEO -* Well, we are seeing mix improvements but we're seeing strong growth in volume. When we look at the number of products we have to - units of work that we produce, we are seeing very strong growth there as well.

171. Defendant Baker was defensive and non-responsive when asked why its DRS subsidiary and DiscoCare shared a fax number prior to the DiscoCare acquisition:

*Madison Spencer - Morgan Stanley - Analyst -* Hi, guys. There seems to be like an elephant in the room. Maybe you can clarify it. You acquired DiscoCare on December 31st of '07. Your subsidiary, Device Reimbursement Services, shared a fax number with DiscoCare back in September, and October and November. Can you just explain that? Were you guys in the same company back then? Did you have a joint venture with them back then?

Mike Baker - ArthroCare - President and CEO - No, it was just a mistake on the website.

*Madison Spencer - Morgan Stanley - Analyst -* How did you - You mistakenly had the same fax number as DiscoCare? That's a coincidence.

*Mike Baker - ArthroCare - President and CEO -* The same people developed the website for DRS that developed the website for DiscoCare, and they just put the wrong fax number on it. As soon as someone pointed it out, we corrected it.

*Madison Spencer - Morgan Stanley - Analyst -* It took you six months to notice that you had the wrong phone number?

*Mike Baker - ArthroCare - President and CEO -* The DRS subsidiary, to be clear, the people are located here in Austin. The subsidiary was established in a different place than DiscoCare. So, do you have another question or is that it?

*Madison Spencer - Morgan Stanley - Analyst -* Yes, but you didn't answer this question yet. It also says it is located in Sanford, Device Reimbursement -

Mike Baker - ArthroCare - President and CEO - That's right.

Madison Spencer - Morgan Stanley - Analyst - Is it located in Sanford?

*Mike Baker - ArthroCare - President and CEO -* That's where it is incorporated, ves.

**Madison Spencer - Morgan Stanley - Analyst - No, is it located there though?** 

*Mike Baker - ArthroCare - President and CEO -* We have a facility in Sanford, and that's where that is located, just like -

*Madison Spencer - Morgan Stanley - Analyst -* So the warehouse in Sanford is where you run it out of?

*Mike Baker - ArthroCare - President and CEO -* Operator, can we move on to the next caller, please?

172. In addition, Defendant Baker responded to questions about reimbursement issues:

**David Lebowitz** - SMH Capital - Analyst - Sure, sure. Just jumping over to the reimbursement issues as well, I know there's certainly been a lots of talk regarding reimbursement of spine and DiscoCare, and I am wondering if you can just talk to reimbursement of the spine business, particularly PDD, and compare and contrast how that really differs from reimbursement in your other areas of business, including sports medicine, ENT, just so we understand how things flush out between the groups?

Mike Baker - ArthroCare - President and CEO - . . . The PDD reimbursement climate, especially in the U.S., has been relatively difficult at the beginning of that launch, because it is a brand new therapy and anything that's new is difficult to get reimbursement for it. We have seen the environment for reimbursement for this therapy improve dramatically in the last 3 years . . . In the U.S., we had our - we began getting success with Government payers like the Department of Defense, and

followed on with success with workmans comp payers, where we have established PDD therapy as reimbursed on the large national workers comp contracts.

Now for the last, better, I guess year and a half, we have been increasing success with getting this therapy paid for by private insurers in the U.S. on a preauthorization basis. We think that as the - what's really driving this is the - the increasing amount of very credible, peer-reviewed scientific data that's available for - to support a documentation of medical necessity and to help to drive positive reimbursement decision. . . . We ultimately expect to see broad-based reimbursement established by all payers in this country, as we have seen in Germany and the U.K. and other major European countries. So there's really nothing - nothing different about PDD than there is about any other new medical procedure. You sort of have to go through this process of accumulating enough data to drive a routine coverage decision, and in advance of that, if patients who are having their procedure paid for private insurance need to have a surgery, then they have to go through a preauthorization process.

**David Lebowitz - SMH Capital - Analyst -**What type of lag time is there typically with such data coming out, and actually getting official reimbursement from these private payers?

Mike Baker - ArthroCare - President and CEO - Well, there's something - to be clear, there are some private payers that already have established routine reimbursement guidelines, and a lot of them haven't. The lag time can be anywhere from the space of a few months to - with some of them it may take several years. So, we will obviously be thinking strategically about which payers are the right ones to approach first as more this data becomes available, and you sort of build on one positive reimbursement decision after another until you have broad-based routine reimbursement across the entire country with all payers. In advance of that, though, you keep doing what we are doing right now, which is doing the extra administrative work that is required to put together the documentation to support a request for medical necessity, which is the basis for a pre-authorization of a procedure that is not routinely reimbursed.

173. For the reasons stated above in Section IV., Substantive Allegations, and as further detailed in ¶97 and herein, the statements made in the 2007 Form 10-K, the accompanying press release, and the February 19, 2008 conference call set forth in ¶164 through ¶172, which touted among other things the Company's revenue growth, increase in gross margin, and Spine business unit growth, were materially false and misleading when made or omitted material facts to make such statements not false or misleading. In addition, they were false and misleading or omitted material facts to make such statements not false or misleading because: (a) the DiscoCare acquisition was

suspicious and had the effect of covering up the Company's true relationship with DiscoCare, the illicit DiscoCare scheme, and inflating ArthroCare's balance sheet (*see*, *e.g.*, ¶38-65; 71-81; 220-221); (b) the Company's decision to target spine and neurosurgeons as customers was in part based on its goal to have them to upcode using more invasive surgery codes so that ArthroCare could raise the price of its SpineWands and increase its revenues and gross product margins (*see*, *e.g.*, ¶44-58; 63-65); (c) the Company's increase in PDD sales was not the result of "an improving reimbursement environment" but the product of the illicit DiscoCare scheme (*see*, *e.g.*, ¶38-65); (d) the Company's gross margin improvement was the result of ArthroCare's artificially inflated prices of its SpineWands as well as its channel stuffing activities (*see*, *e.g.*, ¶41-52; 82-85); and (e) contrary to Defendant Baker's statements, DiscoCare and DRS's shared fax number was not a mistake but because these entities were actually related and DiscoCare and ArthroCare were one and the same (*see*, *e.g.*, ¶41; 72-73; 87).

174. On April 21, 2008, Defendants issued a press release entitled, "ARTHROCARE'S FIRST QUARTER PRODUCT SALES INCREASES 25 PERCENT, NET INCOME INCREASES 30 PERCENT. REVENUE AND PROFIT EXCEED CONSENSUS; COMPANY RAISES GUIDANCE." This press release stated in pertinent part:

ArthroCare Corp. (Nasdaq: ARTC), a leader in developing state-of-the-art, minimally invasive surgical products, reported earnings results for the quarter ended March 31, 2008 with revenue increasing 23 percent, reaching \$91.0 million compared with \$73.7 million in the prior year quarter. Net income increased 30 percent to \$9.3 million, or \$0.34 per share, compared with \$7.1 million, or \$0.25 per share a year ago. Earnings per share exceeded the high end of the company's prior guidance by \$0.02. Results were driven by better than anticipated results in the company's largest business, sports medicine, as well as increased market traction in the company's ENT business. The company's operating profit also showed significant increases.

"This quarter's results again demonstrate the potential of our core platform technology strategy to create value. The significant and sustained investment in R&D that we're making to execute this strategy is generating a stream of innovative new products. These new products allow us to drive rapid growth and because our

approach is platform-driven, we are not overly dependent on any one product or market for our growth," noted Mike Baker, CEO of ArthroCare.

#### **REVENUE**

First quarter of 2008 product sales of \$88.5 million increased 25 percent from \$71.0 million in the first quarter of 2007. Royalties, fees, and other revenue was \$2.5 million in the first quarter of 2008 compared with \$2.7 million in the first quarter of 2007 and represented three percent of total revenue for the first quarter of 2008 and four percent of total revenue for the first quarter of 2007. International product sales increased 31 percent in the first quarter over the first quarter of 2007, led by the sale of sports medicine products in the Company's direct distribution markets and ENT sales in the United Kingdom.

\* \* \*

Sales in the spine business unit during the first quarter of 2008 grew 24 percent compared to the same period in 2007, with spine sales representing 14 percent of product sales in the first quarter of 2008. The company expects spine revenue growth to accelerate throughout 2008 as the recently launched MD SpineWand® and Cavity SpineWand® sales accelerate.

\* \* \*

Product margin was 71 percent in the first quarter of 2008, consistent with product margin of 71 percent in the first quarter of 2007. Operating expenses were \$52.8 million in the first quarter 2008, or approximately 58 percent of total revenue compared to \$44.0 million, or 60 percent of total revenue in the first quarter of 2007....

\* \* \*

- ... Inventories decreased to \$57.2 million from \$61.8 million at December 31, 2007. Accounts receivable was approximately \$80.5 million at March 31, 2008 compared to \$69.9 million at December 31, 2007.
- 175. Also on April 21, 2008, the Company hosted an earnings conference call with various securities analysts to discuss ArthroCare's first quarter 2008 financial results. Defendants Baker and Gluk participated in this conference call. During the opening remarks, Baker stated in pertinent part:
  - ... We now have the first quarter in the books and we are happy to be able to report that the business is continuing to perform extremely well, tracking ahead of plan on both a revenue and earnings per share basis, and that we are on track to accomplish all of our strategic and financial objectives for the year.

In Q1 we saw significant growth in product sales across all of our business segments, with all three segments recording increases of more than 20% for the second quarter in a row . . . . Our spine business continued to grow rapidly . . . .

\* \* \*

... Our spine business recorded revenue growth of just over 24% in Q1, and while the business is on track to meet its objectives for the year, the Q1 numbers were a little below what we expected to see for the quarter. We had expected Q1 growth to be impacted by the integration of DiscoCare into DRS and it was. We had not anticipated a shortage of controllers, and as in the other businesses we spent much of Q1 on back order for spine controllers. This shortage probably impacted this business more than the others, as we currently have a much smaller install base of spine controllers and this business is largely dependent on the acquisition of new customers for its growth. In any event, the acquisition integration is now complete, the controller shortage is being resolved and we believe that this business is on track to accomplish its financial objectives for the year.

Sales of our plasma disc decompression product continued to grow briskly in Q1 and we expect to see this trend continue over the balance of the year...We also expect to see the data from these presentations published in peer-reviewed spine and neurosurgery literature before the end of the year, which will help to continue to drive penetration and improvements in the global reimbursement environment.

\* \* \*

Now while the PDD product line is still the best selling product line in the spine segment. . . .

. . . So all in all we believe that we have plenty of horsepower to meet our spine growth targets for the year and that the spine business is positioned to be a powerful growth driver for the foreseeable future.

## 176. Defendant Gluk made the following comments:

- ... As we've already indicated, our revenue in earnings results were slightly ahead of our expectations for the quarter, with product revenue growth of 25%, total revenue growth of 23% and EPS growth of 36%. At this point I'd like to provide you with some insight into some key income statement and balance sheet trends . . . . Spine revenue growth was 24% over the first quarter of 2007, slightly below our internal expectations due in part to the shortage of spine controllers, but again, we do expect to meet our annual guidance for revenue growth . . . .
- ... Our first quarter product margin of 71% represents a 200 basis point improvement over the first quarter of last year and a four point decline from the fourth quarter of last year. This sequential decline was anticipated by us and we discussed it on the last conference call. The sale of inventory, which was purchased from DiscoCare as part of the acquisition and revalued to market, accounted for approximately two points of auto deterioration . . . Looking forward we expect

margin to continue to improve throughout the year, as the impact of the plant shutdown will be behind us while the material cost reductions and at decisional volume we generate will improve our per unit costs.

177. With respect to 2009 guidance for EPS growth, Defendant Baker stated:

*Ed Shenkan - Needham & Company - Analyst -* And you gave 2009 guidance for the first time with 35% EPS growth. You guys grew earnings 32% in '07. Where does the acceleration come -- 32% in '07. Where does the acceleration come from? We wouldn't expect you to cut back on R&D. Is it that G&A stays at a small level and becomes a smaller percentage of sales, or how do we get this leverage?

Mike Baker - ArthroCare Corp. - President & CEO - . . . One of the things that Mike didn't talk about too much in his script that gives us confidence on gross margin is really we have an ongoing positive mix shift. The products in the Company that are the fastest growing products are, in fact, the highest margin products and that process will continue, not just through '08, but through '09 and beyond.

178. Defendant Baker also addressed a question regarding potential inquiries related to

DiscoCare and related litigation:

Raj Denhoy - Bear, Stearns - Analyst - Okay, fair enough, and then I'll just ask one more. I hate to bring it up but you did mention that the DiscoCare issues in your mind are largely behind the Company and that there are no pending -- or inquiries that you're aware of, any existing or pending inquiries. If you believe what you read -- and you probably shouldn't too much -- there are a number of lawsuits that are out there pending potentially. Does anything out there give you any concern right now or is there anything that's consuming your time on that front still?

Mike Baker - ArthroCare Corp. - President & CEO - No. As far as we're concerned, the NASDAQ inquiry was very comprehensive and completely closes the issue. As to the shareholder lawsuit issue, there has actually been one shareholder lawsuit filed. There were about eight press releases done about it but there was one lawsuit filed. Often when you get one lawsuit, a bunch of other firms will do press releases hoping to find plaintiffs and, in fact, if you look at the lawsuit as it is written, companies always say that these things are without merit but in this case this really is without merit. The lawsuit basically on the face of it is, the things that it's alleging are factually inaccurate and it doesn't meet the standard for a lawsuit of this type. So we basically filed a motion to dismiss the lawsuit the day after it was filed and we believe that the lawsuit should, in fact, be dismissed and if for any reason it's not, then we'll simply go to trial and win on the merits. But if you read what's in the lawsuit -- and it is public available -- and then you read our 10-K, you'll realize that what they're alleging is factually incorrect.

179. Defendant Baker also responded to questions regarding the Company's increase in receivables following the DiscoCare acquisition:

**Bill Plovanic - Canaccord Adams - Analyst -** Okay, and then if I could just -- if I could just ask one more question. In terms of the receivables going up over \$10 million sequentially -- I think that's the question everybody's going to hone in on here -- your revenues were up only \$4 million sequentially on product sales. That's just a big jump and I beg the question of it's hard to see that just not having people focusing on collections would cause that big of a change sequentially. Is there something else at play here? Is this the DiscoCare longer receivables that are impacting your P -- your balance sheet? Is there something else going on?

*Mike Baker - ArthroCare Corp. - President & CEO* - The shore answer is that there are some healthcare receivables when you're billing an insurance company directly that are going to be longer DSOs than when you bill a doctor, but really the big impact on the quarter was exactly what Mike described. We had -- basically the same people who do our collections had to do the integration of this, and so we ended up with DSOs going up to just over 80 days instead of being 77 days, which is what they averaged last year. So we can obviously do better than that and that's what we plan on doing over the balance of the rest of the year . . . .

180. Defendant Baker responded to a question regarding reimbursement practices since the DiscoCare acquisition:

**Brian Weinstein - William Blair - Analyst -** Okay. And then how -- or are you changing your spine reimbursement practices now that DiscoCare is in-house? Is the mix -- within DiscoCare that you guys have talked about within the three buckets, is that consistent with what you guys had said in the past now or is that shifting one way or the other among those buckets?

Mike Baker - ArthroCare Corp. - President & CEO - Well, the future of that business undoubtedly is broad-based private pay coverage nationally and that's what's going to drive the business long term. And obviously that's what all of our efforts are focused on achieving and that's why the large number of clinical presentations and publications that we have on tap for this year are important because that'll give us the ammunition to go back into payers that do not have national coverage policies that are paying for this on a pre-approval or case-by-case basis and get them to establish national coverage. So there's no question that we expect to see that mix shift dynamically but we're not going to go -- we're not going to be in the business of giving quarterly updates on what it is. Obviously we will announce it as we get national coverage decisions from major carriers.

In terms of what's changed with the integration, we've obviously integrated the DiscoCare (inaudible) that we acquired into our DRS subsidiary and we have established a set of OIG compliant, Office and Inspector General compliant, policies and procedures to govern activities of that area and we also make sure the

activities of that area follow those policies and procedures by making them part of our stocks control. So, we had a high degree of confidence that these things were being done correctly before the acquisition and that degree of confidence is even higher today.

181. On May 12, 2008, ArthroCare filed its quarterly report for the first quarter of 2008 on Form 10-Q with the SEC, the period ended March 31, 2008, which was signed by Defendants Baker and Gluk. The 2008 first quarter Form 10-Q reaffirmed the financial results announced in the press release above in ¶174. Specifically, Defendants Baker and Gluk signed false SOX certifications substantially similar to those found in ¶94, above. Further, it contained statements by the Individual Defendants regarding disclosure controls and procedures that were substantially the same as those contained in ¶119, above.

For the reasons stated above in Section IV., Substantive Allegations, , and as further 182. detailed in ¶97 and herein, the statements made in the 2008 first quarter Form 10-Q, the accompanying press release, and the April 21, 2008 earnings conference call set forth in ¶174 through ¶181, which touted among other things, the Company's product sales growth, and explained the Company's increase in receivables and gross margin hit, were materially false and misleading when made or omitted material facts to make such statements not false or misleading. In addition, they were false and misleading or omitted material facts to make such statements not false or misleading because: (a) the DiscoCare acquisition was suspicious and had the effect of covering up the Company's true relationship with DiscoCare, the illicit DiscoCare scheme, (and was responsible for an increase in receivables) and otherwise inflating the Company's balance sheet (see, e.g., ¶38-65; 71-81); (b) Despite Defendant Baker's statement that "we are not overly dependent on any one product or market for our growth," the Company's PDD SpineWand was the key driver of its Spine division (see, e.g., ¶¶63-64; 116); (c) the Company's Spine revenues were not the result of increased penetration and improvements in the global reimbursement environment but rather the illicit DiscoCare scheme (see, e.g., ¶¶38-65); (d) contrary to Defendant Baker's statement that "we had a high degree of confidence that these things were being done correctly before the acquisition," DiscoCare had been at the center of an insurance scam with Arthrocare; and (e) the shareholder lawsuit the Company is facing, as detailed herein throughout, is factually accurate.

## B. Defendants' Violations of GAAP

- 183. As detailed herein, in order to improperly inflate ArthroCare's revenue, gross profit, income from operations, net income, and net income per share, Defendants caused the Company to falsely report its financial results included in ArthroCare's publicly issued financial statements and related earnings releases during the Class Period.<sup>58</sup> These financial results were materially false and misleading and in violation of GAAP<sup>59</sup> and SEC guidance due to the following improper accounting schemes:
- (a) ArthroCare improperly recognized revenue on purported sales to DiscoCare including:
  - (i) premature, inflated, and fictitious revenue in violation of the SEC's revenue recognition requirements under Staff Accounting Bulletin 104; and

ArthroCare's Class Period financial statements and earnings releases issued to the public and filed with the SEC include: SEC Form 10-Q's for the periods ended March 31, 2006, June 30, 2006, September 30, 2006, March 31, 2007, June 30, 2007, September 30, 2007, and March 31, 2008; SEC Form 10-Ks for the periods ended December 31, 2006 and December 31, 2007; SEC Form 8-Ks issued on May 2, 2006, August 3, 2006 October 27, 2006, February 16, 2007, April 27, 2007, July 27, 2007, October 23, 2007, February 19, 2008, and April 22, 2008.

GAAP are those principles recognized by the accounting profession as the conventions, rules, and procedures necessary to define accepted accounting practice at a particular time. SEC Regulation S-X (17 C.F.R. §210.4-01(a)(1)) states that financial statements filed with the SEC that are not prepared in compliance with GAAP are presumed to be misleading and inaccurate, despite footnotes and other disclosure. Regulation S-X requires that interim financial statements must also comply with GAAP, with the exception that interim financial statements need not include disclosure that would be duplicative of disclosures accompanying annual disclosures, per 17 C.F.R. §210.10-01(a).

- (ii) improper and unearned revenue as a result of vastly overcharging for SpineWands in a scheme whereby defendants, DiscoCare and certain physicians inflated reimbursable medical bills in personal injury cases, in violation of FASB Concepts Statement No. 5 Recognition and Measurement in Financial Statements of Business Enterprises;
- (b) ArthroCare improperly recognized revenue on purported sales to several other distributors who received rebates, kickbacks, and other incentives including:
  - (i) premature and inflated revenue as a result of providing purchase price rebates to distributors, in violation of the SEC's revenue recognition requirements under Staff Accounting Bulletin 104;
  - (ii) premature, inflated, and fictitious revenue as a result of providing certain incentives to distributors to engage in channel stuffing, in violation of the SEC's revenue recognition requirements under Staff Accounting Bulletin 104 and FASB Statement No. 48 Revenue Recognition When Right of Return Exists; and
  - (iii) premature and inflated revenue as a result of failing to record offsets to revenue for rebates, commissions, fees, and other kickbacks paid to distributors, in violation of FASB EITF 01-9 "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vender's Products);
- (c) ArthroCare's disclosures regarding revenue recognition were false and misleading and in violation of GAAP and SEC Guidance, specifically SAB 104 and APB Opinion No. 22 Disclosure of Accounting Policies;
- (d) ArthroCare failed to reserve for contingent losses associated with its involvement in a fraudulent medical billing scheme, in violation of FASB Statement No. 5 *Accounting for Contingencies*; and
- (e) ArthroCare improperly accounted for the allocation of the purchase price in the DiscoCare acquisition, in violation of FASB Statement No. 141 *Business Combinations*.
- 184. As a result of these improper accounting schemes, as described herein, ArthroCare materially overstated revenue in each of its quarterly and annual public financial statements and related earnings releases filed with the SEC during the Class Period. In total, ArthroCare overstated

Class Period revenue by at least \$37 million, consisting of more than 5% of all product revenue recorded by the Company during that time. In addition, ArthroCare also materially overstated income from operations, net income, gross profit, net income per share (diluted and basic), and accounts receivable (net of allowance), and understated inventory during the Class Period. The fact that these overstatements are material is not disputed by ArthroCare. On July 21, 2008, the Company announced that its public financial statements for FY2006, FY2007 and Q12008 were materially misstated, could no longer be relied upon, and would be restated:

AUSTIN, TEXAS — July 21, 2008 — ArthroCare Corp (Nasdaq: ARTC) announced today that *it will restate its financial statements* for the years ended December 31, 2006 and 2007, the quarters ended September 30, 2006, December 31, 2006, each of the quarters of 2007 and the quarter ended March 31, 2008 as a result of the determination by the Audit Committee of the Board of Directors on July 20, 2008 that *the financial statements for such periods can no longer be relied upon*.

\* \* \*

Management estimates that the effect of the restatement will be a non-cash reduction in revenue in 2006 of \$4 million to \$7 million and in 2007 of \$20 million to \$25 million. The estimated effect of the restatement on revenue in the first quarter of 2008 will be a reduction of \$2 million to \$5 million. Management estimates that the restatement will result in material reductions in operating income and net income for the annual and quarterly periods being restated.

- 185. The fact that ArthroCare will restate its financial statements is an admission that:
- (a) the financial results originally issued during the Class Period and its public statements regarding those results were materially false and misleading;
- (b) the financial statements reported prior to and during the Class Period were incorrect based on information available to Defendants at the time the results were originally reported; and
  - (c) the financial statements can no longer be relied upon as being accurate.
  - 186. The SEC has reiterated its position regarding restatements:

[T]he Commission often seeks to enter into evidence restated financial statements and the documentation behind those restatements, in its securities fraud enforcement

actions in order, inter alia, to prove the falsity and materiality of the original financial statements [and] to demonstrate that persons responsible for the original misstatements acted with scienter. . . . <sup>60</sup>

187. As admitted by ArthroCare in its July 21, 2008 Form 8-K, and pursuant to GAAP, as set forth in APB No. 20, the type of restatement announced by ArthroCare was to correct for material errors in its previously issued financial statements. *See* APB No. 20, ¶¶7-13. Moreover, SFAS No. 154, ¶25, *Accounting Changes and Error Corrections*, states: "Any error in the financial statements of a prior period discovered subsequent to their issuance shall be reported as a priorperiod adjustment by restating the prior-period financial statements." Thus, GAAP provides that financial statements should be restated in order to correct an error in previously issued financial statements. Because ArthroCare's restatement is due to an "error," the restatement is an admission by ArthroCare that its previously issued financial results and its public statements regarding those results were false.

## 1. ArthroCare Improperly Recognized Revenue, in Violation of GAAP, on Purported Sales Transactions with DiscoCare

and prematurely recognized revenue in violation of GAAP, on sales to DiscoCare. These purported sales were based on a scheme whereby ArthroCare represented that DiscoCare was a traditional third party customer purchasing ArthroCare's products for resale. However, as alleged herein, DiscoCare was a closely affiliated entity utilized by ArthroCare to circumvent GAAP revenue recognition rules in order to record premature, inflated, and even fictitious revenue. In fact, the purported sales with

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In re Sunbeam Sec. Litig., No. 98-8258-Civ-Middlebrooks, Brief of the United States Securities and Exchange Commission as Amicus Curiae Regarding Defendants' Motions In Limine to Exclude Evidence of the Restatement and Restatement Report at 2 (S.D. Fla. Feb. 22, 2002).

DiscoCare were contingent upon the potential and uncertain settlement of personal injury lawsuits and ArthroCare was never assured of receiving payment.

- a. ArthroCare Recorded Premature and Inflated Revenue in Violation of the SEC's Revenue Recognition Requirements Under Staff Accounting Bulletin 104
- 189. FASB Statement of Financial Accounting Concepts No. 5 ("FASCON 5") clearly and concisely states that revenue should not be recognized until it is both realized (or realizable) and earned. SAB 104 has further reiterated revenue recognition rules under GAAP by requiring that revenue can be recognized only when all of the following criteria are met:
  - 1. Persuasive evidence of an arrangement exists;
  - 2. Delivery has occurred or services have been rendered;
  - 3. The seller's price to the buyer is fixed or determinable; and
  - 4. Collectability is reasonably assured.
- 190. ArthroCare's recognition on purported sales to DiscoCare was improper, as the sales did not meet the criteria listed in SAB 104 for the following reasons:

#### (1) No Persuasive Evidence of an Arrangement

191. ArthroCare's recognition of revenue on sales transactions with DiscoCare violated the SAB 104 requirement that "persuasive evidence of arrangement exists" prior to revenue being recognized. The nature of the relationship between ArthroCare and DiscoCare, which amounted to a sales agent relationship, demonstrates that a buyer/seller arrangement did not in fact exist between the two, and thus precluded revenue recognition under SAB 104. This cannot be disputed, as ArthroCare disclosed the following in its July 20, 2008 Form 8-K announcing the restatement of its previously issued financial statements:

The relationship between the Company and DiscoCare, Inc. during the periods being restated was a sales agent relationship, rather than that of a traditional distributor.

- 192. Accordingly, because DiscoCare was in substance, the sales arm of ArthroCare even before the December 31, 2007 acquisition, "persuasive evidence of an arrangement" between buyer and seller as required under SAB 104 did not exist.
- 193. Additionally, SAB 104 states that an "arrangement" does not exist and revenue can not be recognized when:

# ... the buyer acquiring the product for resale does not have economic substance apart from that provided by the seller.

As described above, DiscoCare was at best a sales agent of ArthroCare, and had little, if any, economic substance apart from that provided by ArthroCare.

- 194. Finally, the admitted fact that DiscoCare was a sales agent rather than a true customer prohibited ArthroCare from recognizing revenue upon shipment because SAB 104 also provides that revenue recognition is not appropriate when, in substance, the seller retains the risks and rewards of ownership of the product and the title does not pass to the buyer. As a sales agent, DiscoCare did not, in substance, take title to ArthroCare's products.
- 195. Beyond DiscoCare, ArthroCare did not have 'evidence of an arrangement' with any other third party involved in the sale of ArthroCare's Spine Wands using the DiscoCare Model. As described herein, no other party to the sales transactions, including the medical facilities and surgeons that used the products or the patients themselves, had any obligation to pay for the products prior to settlement of the related personal injury lawsuits. As a result, ArthroCare, in substance, had no persuasive evidence of a true sales arrangement with any of the parties involved.

## (2) No Fixed Sales Price and No Assurance of Collectability

196. ArthroCare's sales transactions with DiscoCare also violated the SAB 104 requirements that "the seller's price to the buyer is fixed or determinable" and "collectability is reasonably assured," because the entire sales arrangement, including the price paid by DiscoCare

(*i.e.*, the price ultimately paid by the personal injury attorney from whom DiscoCare collected the money from), as well as ArthroCare's ability to collect any money at all, was contingent upon a favorable outcome of personal injury litigation. Without a fixed price, <sup>61</sup> much less any guarantee of payment at all, SAB 104 clearly states that ArthroCare could not recognize revenue on these supposed "sales" transactions with DiscoCare until known amounts of cash were received upon the settlement of the related personal injury claims.

197. As described herein, the end-user payors for the products involved in ArthroCare's transactions with DiscoCare were the personal injury attorneys who referred patients to the medical clinics, or the casualty insurance companies who actually paid to settle the suit. The doctors, medical facilities, or the patients themselves did not have any obligation to pay for the ArthroCare products that were provided to them. Instead, as alleged herein, the ArthroCare SpineWands were provided by DiscoCare to doctors or medical facilities at no charge in return for an LOP from a personal injury attorney, where later payment, if at all, came from the settlement of personal injury litigation.

198. SAB 104 states that a sales "arrangement may not specify that payment is contingent upon subsequent resale." ArthroCare's sales transactions with DiscoCare, as described herein, *were* contingent and therefore further violated the requirements of SAB 104. Specifically SAB 104 precludes revenue recognition when:

- (a) the buyer does not pay the seller at the time of sale, and the buyer is not obligated to pay the seller at a specified date or dates. [or]
- (b) the buyer does not pay the seller at the time of sale but rather is obligated to pay at a specified date or dates, and the buyer's obligation to pay is contractually or implicitly excused until the buyer resells the product....

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SAB 104 defines a "fixed fee" as a "fee required to be paid at a set amount that is not subject to refund or adjustment."

199. As a result of the contingent nature of the sales using the DiscoCare Model, ArthroCare failed to meet the SAB 104 criteria requiring that "the seller's price to the buyer is fixed or determinable" and "collectability is reasonably assured," and was precluded from recognizing revenue until known amounts of cash was received upon the settlement of the related personal injury claims.

## b. ArthroCare Recorded Improper and Unearned Revenue in Violation of FASB Concepts Statement No. 5

- 200. ArthroCare also improperly recorded revenue by massively overcharging for its Spine Wands, in a scheme as described herein, whereby Defendants, DiscoCare, and certain physicians artificially inflated reimbursable medical bills in personal injury cases. Defendants and DiscoCare accomplished this by fraudulently overcharging for the SpineWands by five to six fold, and by encouraging physicians to fraudulently upcode the PDD procedure to CPT code 63056, a code utilized for a substantially different, more invasive procedure that, when appropriately performed, warranted a much higher reimbursement value.
- 201. GAAP requires that, prior to revenue recognition, an entity must provide the actual product or service that entitles it to the revenue to be received:

"[r]evenues are not recognized until earned... revenues are considered earned when the entity has substantially accomplished what it must do to be entitled to the benefits represented by the revenues." *See* FASB Statement of Financial Accounting Concepts No. 5, ¶83(b).

- 202. In this case, ArthroCare had neither earned nor was entitled to the revenue booked on these sales because payment for the fraudulently inflated price of the SpineWand could not have occurred but for the improper upcoding of the procedure code.
- 203. As a result of ArthroCare's improper revenue recognition practices with respect to DiscoCare detailed above, and its fraudulent practice of massively overcharging for its SpineWands in the scheme to fraudulently inflate medical billings as part of the DiscoCare Model,

ArthroCare's revenues, 62 gross profit, net income and net income per share were improperly and materially inflated throughout the Class Period.

- 2. Arthrocare Improperly Recognized Revenue on Purported Sales to Several Other Distributors Who Received Rebates, Kickbacks and Other Incentives
- 204. In addition to the above accounting schemes and improper revenue recognition involving DiscoCare, ArthroCare further inflated revenue in violation of GAAP, on sales transactions with several other key distributors. As part of this improper accounting scheme, ArthroCare improperly recognized revenue on sales transactions with several key distributors who received price protection rebates, commissions, kickbacks, and other incentives as a component of the sales arrangements. These payments and incentives were used by ArthroCare to induce the distributors to "purchase" more products or "pay" higher prices than they otherwise would have agreed to. As a result of these payments and incentives, ArthroCare recorded premature and inflated revenue during the Class Period as described below.
  - a. ArthroCare Recognized Premature and Inflated Revenue as a Result of Providing Purchase Price Rebates to Distributors, in Violation of the SEC's Revenue Recognition Requirements Under Staff Accounting Bulletin 104
- 205. ArthroCare recorded premature and inflated revenue on sales transactions with certain key distributors which were, in substance, consignment sales because the actual sales price to be paid by the distributors was contingent upon the resale price (if and when the distributors

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In addition to materially inflating reported revenues as described above, this practice also resulted in a material overstatement of ArthroCare's reported accounts receivable, and understatement of inventory. This is corroborated by the fact that at the time of ArthroCare's acquisition of DiscoCare on December 31, 2007, ArthroCare still had as much as \$13.5 million in unpaid accounts receivable from DiscoCare. In addition, DiscoCare still held as much as \$8 million in excess ArthroCare product in inventory. This enormous stockpile of excess inventory as well as the accounts receivable all came back onto ArthroCare's books upon the acquisition of DiscoCare.

rebates from ArthroCare for any shortfall (when compared to the original price paid to ArthroCare) in their resale price to end-user customers. As a result of the price protection rebates paid to distributors, GAAP prohibited ArthroCare from recognizing revenue until the distributors resold the products to end-user customers and the price protection rebates could be calculated because ArthroCare did not have a 'fixed and determinable sales price'- as required by GAAP, specifically SAB 104.

206. There is no dispute that ArthroCare's accounting for such transactions was improper. As noted in its July 21, 2008 Form 8-K restatement announcement shown below, as the Company admitted to improperly overstating revenue on shipments to several key distributors in this manner:

[T]he sales price of products sold to State of the Art Medical Products, Inc. ("SOTA"), Boracchia & Associates and Clinical Technology, Inc. cannot be considered fixed or determinable upon shipment by ArthroCare during the periods being restated. the Company will therefore account for sales by ArthroCare of products to each of these entities from the third quarter of 2006 to March 31, 2008, under a sell-through revenue recognition method that is appropriate for both of these situations, as opposed to a sell-in method – under the sell-through method, revenue is not recognized until after the surgery is performed or a subsequent sale to another customer occurs.

\* \* \*

The sales prices to SOTA, Boracchia, and Clinical Technology were not fixed or determinable under Staff Accounting Bulletin 104, "Revenue Recognition," which sets forth four criteria which are necessary before revenue can be recognized, including that sales prices are required to be fixed or determinable, due to rebates to the distributors if the distributors sold the products at prices below their purchase price from ArthroCare.

207. Because of the contingent nature of ArthroCare's sales to these key distributors, in which the true sale of ArthroCare's products was not finalized until the distributors could find enduser customers and negotiate a price, the recognition of revenue by ArthroCare upon initial

shipment also violated the SAB 104 criterion requiring that "persuasive evidence of an arrangement exists" before revenue can be recognized. SAB 104 states in pertinent part:

Products delivered to a consignee pursuant to a consignment arrangement are not sales and *do not qualify for revenue recognition until a sale occurs*. The staff believes that revenue recognition is not appropriate because *the seller retains the risks and rewards of ownership of the product* and title usually does not pass to the consignee.

Other situations may exist where title to delivered products passes to a buyer, but the substance of the transaction is that of a consignment... The staff believes that the presence of one or more of the following characteristics in a transaction precludes revenue recognition even if title to the product has passed to the buyer.

The buyer has the right to return the product and:

- (a) the *buyer does not pay the seller at the time of sale*, and the buyer is not obligated to pay the seller at a specified date or dates.
- (b) the buyer does not pay the seller at the time of sale but rather is obligated to pay at a specified date or dates, and the buyer's obligation to pay is contractually or implicitly excused until the buyer resells the product or subsequently consumes or uses the product.
- 208. Many of ArthroCare's key distributors had no risks associated with the purchase and resale of ArthroCare's products because they were assured of recouping any shortfalls in the form of price protection rebates. As a result, these sales were, in substance, consignment sales and ArthroCare did not have "*persuasive evidence of an arrangement*" as contemplated under SAB 104.
  - b. ArthroCare Recognized Premature, Inflated, and Fictitious Revenue as a Result of Providing Certain Incentives to Distributors to Engage in Channel Stuffing in Violation of the SEC's Revenue Recognition Requirements Under Staff Accounting Bulletin 104 and FASB Statement No. 48
- 209. ArthroCare further inflated revenue on sales to many of these same key distributors by engaging in channel stuffing whereby ArthroCare provided certain incentives to these distributors to induce them to accept excess products. The terms of these various inducements,

including extended payment terms and the right to return unsold product, caused the particular transactions to fail SAB 104 revenue recognition criteria.

- 210. For example, as described at ¶84, ArthroCare extended payment terms to certain key distributors that were extended to "120 days or whatever was needed." As a result, the sales, in substance, constituted a *de facto* contingent arrangement that is, the extended payment term was designed to be so generous, that it would allow the distributor enough time to both sell the product and get paid from the end user before the original payment to ArthroCare was due. As a result of the contingent nature of these sales arrangements, such channel stuffing sales violated the SAB 104 criterion requiring that "Collectibility was reasonably assured" before revenue can be recognized. Additionally, SAB 104 precludes revenue recognition if the "The buyer has the right to return the product and . . . and the buyer is not obligated to pay the seller until the buyer resells the product," and also precludes revenue recognition when the "the seller retains the risks and rewards of ownership of the product."
- 211. In other examples of improper revenue recognition on channel stuffing activities during the Class Period, ArthroCare allowed distributors to return the stuffed product if they could not sell it. For example, as described by the East Coast Manager of ENT at ¶83, ArthroCare also provided these distributors the right to return any unsold products. By allowing distributors the right to return unsold products and by not reserving a legitimate estimate for returns or any other contingency against the reported revenue, ArthroCare also violated FASB No 48 *Revenue Recognition When Right of Return Exists*. FAS 48 clearly and concisely states:

If an enterprise sells its product but *gives the buyer the right to return the product*, revenue from the sales transaction shall be recognized at time of sale *only if all of the following conditions are met*:

a. The seller's price to the buyer is substantially fixed or determinable at the date of sale.

- b. The buyer has paid the seller, or the buyer is obligated to pay the seller and the obligation is not contingent on resale of the product.
- c. The buyer's obligation to the seller would not be changed in the event of theft or physical destruction or damage of the product.
- d. The buyer acquiring the product for resale has economic substance apart from that provided by the seller.
- e. The seller does not have significant obligations for future performance to directly bring about resale of the product by the buyer.
- f. The amount of future returns can be reasonably estimated
- 212. SAB 104 clearly states that if a sales transaction fails to meet all of the conditions of FAS 48, as outlined above, "no revenue may be recognized until those conditions are subsequently met or the return privilege has substantially expired." ArthroCare ignored these well established accounting rules, and improperly recognized revenue on the channel stuffing sales to distributors anyway.
  - c. ArthroCare Recognized Premature and Inflated Revenue as a Result of Failing to Record Offsets to Revenue for Rebates, Commissions, Fees, and Other Kickbacks Paid to Distributors, in Violation of FASB EITF 01-9
- 213. ArthroCare further inflated revenue in violation of GAAP, on sales transactions with many of these same key distributors by failing to properly offset the gross revenue reported, by the amount of the significant payments made to these distributors including the rebates described above, commissions, marketing fees, and other kickbacks. These various fees paid to the distributors were significant and in reality, were simply a way of reducing the purchase price. Again, this is not in dispute. In its July 21, 2008 Form 8-K announcing the restatement of its previously issued financial statements, as shown below, the Company admitted to improperly failing to reduce revenue by the amount of these payments to distributors, in violation of GAAP,

specifically EITF 01-9 Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products):

In addition to the sell-in method to the sell-through revenue recognition method for the four entities discussed above, *the restatement will correct errors identified by management regarding*:

the classification to record as an offset to revenue for commissions paid by ArthroCare to SOTA, Clinical Technology and Arthroscopy & Medical Equipment International, Inc. on products purchased directly by the distributor as principal and subsequently resold to third parties previously recorded as sales and marketing expense;

the classification to record as an offset to revenue of distribution and marketing fees paid to SOTA, Boracchia, Frontier Medical, Inc. and Clinical Technology previously recorded as sales and marketing expense that did not meet the criteria of EITF 01-9 "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vender's Products);"

214. By making these payments to distributors, in the form of commissions, various fees, price protection rebates, and other kickbacks, ArthroCare effectively incentivized the distributors to purchase more products than they otherwise would have and/or agree to higher purchase prices than the otherwise would have because the distributors knew they would be receiving subsequent payments from ArthroCare to offset the original purchase. However, rather than offsetting (reducing) the inflated revenue the Company had originally recorded by the amount of these payments, the Company buried these payments as "sales and marketing" expenses. Because sales and marketing expenses are *not* included in the calculation of gross profit, ArthroCare was able to overstate both revenues and gross profits- two key metrics followed closely by analysts and investors every quarter. ArthroCare's accounting was a clear violation of GAAP, specifically FASB Emerging Issues Task Force Issue No. 01-9, which, clearly and concisely required that the type of payments made by ArthroCare to its distributors be accounted for as a reduction of revenue. Specifically, EITF 01-9 states:

The Task Force reached a consensus that cash consideration (including a sales incentive) given by a vendor to a customer is presumed to be a reduction of the

selling prices of the vendor's products or services and, therefore, should be characterized as a reduction of revenue when recognized in the vendor's income statement.

\* \* \*

The Task Force observed that . . . slotting fees and similar product development or placement fees [are generally required] to be characterized as a reduction of revenue.

\* \* \*

A vendor agrees to reimburse a reseller or retailer up to a specified amount for shortfalls in the sales price received by the retailer for the vendor's products over a specified period of time. Buydown programs generally involve a vendor agreeing to reimburse, compensate, or issue credit memos to a reseller or retailer for the retailer's decreased revenue per unit for specific products during a specified promotion period . . . Other related forms of vendor consideration to a retailer include, but are not limited to, shortfalls, factory incentives, dealer holdbacks, price protection, and factory-to-dealer incentives.

\* \* \*

Buydowns. . . should always be characterized as a reduction of revenue.

- 3. ArthroCare's Disclosures Regarding Revenue Recognition Were False and Misleading and in Violation of GAAP and SEC Guidance
- 215. ArthroCare was required by GAAP and SEC rules, including SAB 104 and APB Opinion No. 22 *Disclosure of Accounting Policies*, to disclose in detail its revenue recognition accounting policy, in the footnotes to its financial statements in each of its publicly issued Forms 10-K and 10-Q. SAB 104 clearly and concisely states this requirement, as follows:

A registrant should disclose its accounting policy for the recognition of revenue pursuant to [APB] Opinion 22. Paragraph 12 thereof states that "the disclosure should encompass important judgments as to appropriateness of principles relating to recognition of revenue . . ."

216. With regard to its revenue recognition policy, ArthroCare made the following disclosures during the Class Period:

Revenue Recognition and Allowance for Doubtful Accounts

The Company recognizes product revenue after shipment of its products to customers has occurred, any acceptance terms have been fulfilled, no significant contractual obligations remain, and collection of the related receivable is reasonably assured. Revenue is reported net of a provision for estimated product returns. [SEC Form 10-Q's for periods ended 3/31/06, 6/30/06, 9/30/06; SEC Form 10-K for period ended 12/31/06]

Revenue Recognition and Allowance for Doubtful Accounts

The Company recognizes product revenue in accordance with SEC Staff Accounting Bulletin No. 104, Revenue Recognition in Financial Statements ("SAB 104"). Under SAB 104, revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is fixed and determinable and collectibility is reasonably assured. Generally, the criteria are met upon shipment of the Company's products.... [SEC Form 10-Q's for periods ended 3/31/07, 6/30/07, 9/30/07]

Revenue Recognition and Allowance for Doubtful Accounts

The Company recognizes product revenue in accordance with SEC Staff Accounting Bulletin No. 104, Revenue Recognition in Financial Statements, or SAB 104. Under SAB 104, revenue is recognized when there is persuasive evidence of an arrangement, delivery has occurred or services have been rendered, the sales price is fixed and determinable and collectibility is reasonably assured. Generally, the criteria are met upon shipment of the Company's products....[SEC Form 10-K for period ended 12/31/07]

- 217. These disclosures were materially false and misleading and in violation of the disclosure requirements included in SAB 104 and APB No. 22 because, as alleged in ¶¶38-65 and 82-85:
- (a) Collection was *not* reasonably assured on sales to DiscoCare and several of ArthroCare's largest distributors;
- (b) Persuasive evidence of an arrangement did *not* in fact exist on sales to DiscoCare in personal injury cases, and transactions with distributors, whereby sales terms were completely flexible with regard to product return, payment time frame;
- (c) The criteria for revenue recognition under SAB 104 were *not* generally met upon shipment of the Company's products; and

- (d) ArthroCare did *not* provide an adequate provision for product estimated returns.
- 218. Additionally, the Company intentionally failed to disclose its revenue recognition policy in its Form 10-Q for the period ended March 31, 2008. Similar to the false disclosures shown above, the omission of its revenue recognition policy also violated the disclosure requirements of SAB 104 and APB Opinion No. 22 and resulted in the issuance of false and misleading financial statements.
- 219. In addition to disclosing its revenue recognition accounting policy, SAB 104 requires additional revenue disclosures for the following types of revenue transactions or events:
  - Shipments of product at the end of a reporting period that significantly reduce customer backlog and that reasonably might be expected to result in lower shipments and revenue in the next period. [i.e., channel stuffing]
  - Granting of extended payment terms that will result in a longer collection period for accounts receivable (regardless of whether revenue has been recognized).
  - Changing trends in shipments into, and sales from, a sales channel or separate class of customer that could be expected to have a significant effect on future sales or sales returns.
  - An increasing trend toward sales to a different class of customer, such as a reseller distribution channel that has a lower gross profit margin than existing sales that are principally made to end users.

As described herein, ArthroCare was subject to numerous transactions and events that are covered by the disclosure requirements described above including sales transactions with DiscoCare and other distributors. Despite these numerous revenue transactions and events, ArthroCare failed to make *any* additional revenue disclosures in its publicly issued financial statements, in violation of SAB 104.

- 4. ArthroCare Improperly Accounted for the Allocation of the DiscoCare Acquisition Purchase Price in Violation of FASB Statement No. 141
- 220. ArthroCare improperly accounted for the purchase price of its acquisition of DiscoCare as of December 31, 2007, as if DiscoCare was a legitimate, arms-length third party distributor. ArthroCare, however, knew DiscoCare was not in fact an arms-length distributor prior to the formal acquisition, but rather DiscoCare was merely the sales arm or "sales agent" of ArthroCare. ArthroCare does not dispute this. In its July 21, 2008 Form 8-K, the Company announced it would restate its financials to correct its improper accounting for the merger:

In addition to the charges from the sell-in method to the fell-through revenue recognition method for the four entities discussed above, the restatement will correct errors identified by management regarding . . . the allocation of the purchase price for the DiscoCare acquisition or December 31, 2007 under FAS 41, "Business Combinations" as a result of the conclusion that DiscoCare was an agent prior to the acquisition, not a distributor; . . . .

- 221. Because ArthroCare was fully aware that DiscoCare was a sales agent prior to the acquisition, ArthroCare knew or was reckless in not knowing that it could not allocate the acquisition purchase price as if DiscoCare was an arms-length third party customer. (*See* ¶¶38-65; 72-73).
  - 5. ArthroCare Failed to Reserve for Contingent Losses
    Associated with its Involvement in a Fraudulent Medical
    Billing Scheme, in Violation of FASB Statement No. 5
    Accounting for Contingencies
- 222. As a result of Defendants' improper involvement in the DiscoCare Model, Defendants exposed the Company to significant material current and recurring future costs and liabilities when the truth about Defendants' fraud came to light. These foreseeable contingent losses include but were not limited to legal costs and fines that were likely to be incurred to defend the Company against regulatory and legal action, and potential disgorgement of the overcharged amounts for DiscoCare Model SpineWands.

- 223. GAAP requires the accrual of a loss contingency by a charge to income if, at the time the financial statements are issued, it is probable that a contingent liability or potential loss has been incurred, and the loss can be reasonably estimated. If such contingent loss is "likely" but cannot be reasonably estimated, a disclosure describing the contingent liability in the footnotes to the publicly filed financial statements is required. *See* Statement of Financial Accounting Standards No. 5, "Accounting for Contingencies," ¶8-11.
- 224. Accordingly, to comply with GAAP, ArthroCare was required to have accrued a reserve for the contingent costs, or, at a minimum, to have disclosed the potential for such contingent costs. However, it never did. As a result of ArthroCare's failure to reserve for these contingent liabilities, ArthroCare's operating income, net income and earnings as reported in its Forms 10-K and 10-Q filed with the SEC during the Class Period were materially overstated.

# 6. ArthroCare's Financial Statements Violated Fundamental Concepts of GAAP and SEC Guidance

- 225. In addition to the above-referenced departures from GAAP and SEC guidance, as a result of the Defendants' accounting improprieties, ArthroCare presented its financial results in a manner that violated the following fundamental accounting principles:
- (a) The principle that financial reporting should provide information that is useful to present and potential investors and creditors and other users of the financial reports in making rational investment, credit, and similar decisions (FASB Statement of Concepts No. 1, ¶34);
- (b) The principle that financial reporting should provide information about the economic resources of an enterprise, the claims to those resources, and the effects of transactions, events, and circumstances that change resources and claims to those resources (FASB Statement of Concepts No. 1, ¶40);
- (c) The principle that financial reporting should provide information about an enterprise's financial performance during a period. Investors and creditors often use information

about the past to help in assessing the prospects of an enterprise. Thus, although investment and credit decisions reflect investors' expectations about future enterprise performance, those expectations are commonly based, at least partly, on evaluations of past enterprise performance (FASB Statement of Concepts No. 1, ¶42);

- (d) The principle that financial reporting should provide information about how management of an enterprise has discharged its stewardship responsibility to owners (stockholders) for the use of enterprise resources entrusted to it (FASB Statement of Concepts No. 1, ¶50);
- (e) The principle that financial reporting should be reliable in that it represents what it purports to represent. That information should be reliable as well as relevant is a notion that is central to accounting (FASB Statement of Concepts No. 2, ¶58-59);
- (f) The principle of completeness, which means that nothing is left out of the information that may be necessary to insure that it validly represents underlying events and conditions (FASB Statement of Concepts No. 2, ¶79);
- (g) The principle that conservatism be used as a prudent reaction to uncertainty to try to ensure that uncertainties and risks inherent in business situations are adequately considered (FASB Statement of Concepts No. 2, ¶95);
- (h) The principle that revenues and gains should not be recognized until they are both earned and realizable (FASB Statement of Concepts No. 5, ¶83); and
- (i) The principle that if collectability of assets received for products, services, or other assets is doubtful, revenues may be recognized on the basis of the cash received (FASB Statement of Concepts No. 5, ¶84).

## VII. ADDITIONAL SCIENTER ALLEGATIONS

226. The Individual Defendants acted with scienter in that they knew or recklessly disregarded that the public documents and statements issued or disseminated in the name of the

Company were materially false and misleading; and knowingly or severely recklessly substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violators of the federal securities laws.

- 227. Indeed, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding ArthroCare and its business practices, their control over and/or receipt of ArthroCare's allegedly materially misleading misstatements and/or their associations with the Company that made them privy to confidential proprietary information concerning ArthroCare, were active and culpable participants in the fraudulent scheme alleged herein. The Individual Defendants knew and/or severely recklessly disregarded the falsity and misleading nature of the information, which they caused to be disseminated to the investing public. The ongoing fraud as described herein could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and/or severe recklessness and complicity of the personnel at the highest level of the Company, including the Individual Defendants.
- 228. In addition to the numerous allegations throughout the Complaint, herein incorporated by reference, demonstrating the Individual Defendants' scienter, for the reasons further detailed herein, each of the Individual Defendants had knowledge of or recklessly disregarded that the public statements and documents the Company issued or disseminated were materially false and misleading. (*see*, *e.g.*, Sec. IV).
- 229. Defendants also undertook the affirmative obligation to obtain knowledge in order to ensure that the Company's disclosures to the market were truthful by executing SOX certifications (see, e.g., ¶94). Moreover, Individual Defendants' scienter is established in light of the Company's admittedly historical weak internal controls that necessitated that they perform "additional analysis and other post-closing procedures to ensure that the condensed consolidated financial statements were prepared in accordance with generally accepted accounting principles." See ¶95, above.

## 1. Individual Defendants' Suspicious Insider Trading

230. While in possession of non-public adverse information regarding the Company's true relationship with DiscoCare, their illicit scheme to raise revenues, and the Company's channel stuffing activities, beginning on April 3, 2006, the Individual Defendants and Company insiders took full advantage of the artificial inflation of ArthroCare's common stock caused by Defendants' misrepresentations. In fact, the Individual Defendants disposed of huge quantities of their stock and reaped massive proceeds. For instance, Defendant Baker sold 317,945 shares of common stock for proceeds of more than \$15 million. This amounted to 73.86% of his common stock holdings. Although some of these sales occurred prior to the official start of the Class Period, they occurred during the second quarter of 2006, when Defendants were already fully immersed in the illicit DiscoCare scheme.

4/3/2006	67,000	\$47.15	\$3,159,050
4/4/2006	13,000	\$45.55	\$592,150
8/10/2006	16,221	\$46.00	\$746,166
8/10/2006	4,300	\$46.11	\$198,273
8/14/2006	59,479	\$46.00	\$2,736,034
10/2/2006	77,990	\$46.15	\$3,599,239
7/27/2007	19,082	\$50.00	\$954,100
7/27/2007	500	\$50.02	\$25,010
7/30/2007	20,000	\$52.00	\$1,040,000
8/3/2007	19,900	\$54.00	\$1,074,600
8/3/2007	100	\$54.02	\$5,402
8/7/2007	11,432	\$56.00	\$640,192
8/7/2007	900	\$56.01	\$50,409
8/7/2007	600	\$56.06	\$33,636
8/7/2007	200	\$56.05	\$11,210
8/7/2007	100	\$56.02	\$5,602
8/7/2007	100	\$56.07	\$5,607
8/21/2007	1,000	\$56.00	\$56,000
8/22/2007	6,041	\$56.00	\$338,296
	317,945		\$15,270,976

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**\$2.450.050** 

1/2/2006

67.000

231. Likewise, Defendant Gluk sold 21,061 shares of stock for proceeds of more than \$1 million, representing 54.69% of his common stock holdings.

4/3/2006	300	\$47.88	\$14,364
5/1/2006	150	\$46.00	\$6,900

8/10/2006	1,000	\$46.00	\$46,000
8/10/2006	150	\$46.00	\$6,900
9/18/2006	3.000	\$48.00	\$144,000
9/18/2006	300	\$48.00	\$14,400
9/19/2006	150	\$48.00	\$7,200
10/5/2006	1,000	\$48.00	\$48,000
10/5/2006	150	\$48.00	\$7,200
12/4/2006	433	\$42.12	\$18,238
7/26/2007	1,000	\$48.00	\$48,000
7/26/2007	450	\$48.00	\$21,600
7/27/2007	2,000	\$48.60	\$97,200
8/1/2007	1,000	\$50.00	\$50,000
8/1/2007	150	\$49.88	\$7,482
9/4/2007	1,000	\$56.88	\$56,880
9/4/2007	150	\$56.89	\$8,534
10/1/2007	1,000	\$56.04	\$56,040
10/1/2007	150	\$56.45	\$8,468
11/1/2007	1,000	\$65.50	\$65,500
11/1/2007	150	\$64.93	\$9,740
12/3/2007	1,000	\$53.18	\$53,180
12/3/2007	466	\$51.31	\$23,910
12/3/2007	150	\$54.40	\$8,160
1/2/2008	1,000	\$48.09	\$48,090
1/2/2008	150	\$49.35	\$7,403
2/25/2008	160	\$41.09	\$6,574
2/25/2008	2	\$41.11	\$82
4/29/2008	3,000	\$48.00	\$144,000
4/29/2008	450	\$48.00	\$21,600
	21,061		\$1,055,644

- 232. The Individual Defendants' stock sales were unusual and suspicious in that such sales were executed at times calculated to maximize their personal benefit from the artificial inflation of ArthroCare's stock price. Both Individual Defendants began trading shortly after the Company's DiscoCare Model was implemented and continued throughout the Class Period until the spring of 2008. During this time, ArthroCare's stock traded at prices over \$60.00 and, artificially inflated by Defendants' misrepresentations, exceeded \$64.00 on several occasions in the Class Period. Accordingly, the Individual Defendants' and Company insiders' stock sales were conspicuously well-timed.
- 233. Further, the stock sales were unusual and suspicious in amount. Defendant Baker sold 317,945 shares of common stock for \$15,270,976 in proceeds between April 3, 2006 and

August 22, 2007. In so doing, Defendant Baker liquidated 73.86% of his common stock holdings.

These sales were also unusual in amount in that during this time period, Defendant Baker sold

almost as much stock as he had during the prior six years. Indeed, between February 4, 2000 and

February 23, 2006, Defendant Baker only sold 437,800 shares for proceeds of \$18,235,575.

234. Defendant Baker's accounting machinations and sale of stock at inflated prices is

nothing new. Defendant Baker has historically taken aggressive accounting positions to increase the

Company's revenues and stock price for personal gain. In 2000, ArthroCare booked licensing and

royalty fees from multiyear contracts all at once at the time its contracts were signed.<sup>63</sup> Licensing

and royalty fees amounted to 10% of the Company's revenues for the first six months of 2000 and

booking these fees upfront helped the Company's high growth earnings estimates.<sup>64</sup> Although

ArthroCare knew that the SEC would be issuing a pronouncement requiring licensing fees to be

issued over the life of an agreement, ArthroCare delayed as long as possible in implementing this

methodology to keep its revenues elevated in order to meet its earnings estimates.<sup>65</sup> This move

enabled Baker to sell shares of ArthroCare stock for \$10.6 million in proceeds when the Company's

stock price hit its high.<sup>66</sup>

235. Likewise, Defendant Gluk's stock sales were unusual and suspicious in amount. As

detailed above, Defendant Gluk sold 21,061 shares of stock for proceeds of more than \$1,055,644.

Elizabeth MacDonald, *Jam Today or Jam Tomorrow Tech Outfits like to front-load their licensing income. The game's over but some put off the day of reckoning*, October 30, 2000, available at http://forbes.com/forbes/2000/1030/6612064a\_print.html (last visited Sept. 23, 2008), attached hereto as Exhibit M.

<sup>&</sup>lt;sup>64</sup> *Id*.

<sup>65</sup> *Id.* 

<sup>&</sup>lt;sup>66</sup> *Id*.

This amount was unusual in that it represented 54.69% of Gluk's common stock holdings. Moreover, it was suspicious in that Gluk's Class Period trades were his only stock sales since he started with the Company in December of 2004.

236. According to their SEC filings, Defendants may have sold some or all of their stock pursuant to Rule 10b5-1 plans. Although Plaintiffs are unaware of the details of these plans because they have not been filed with the SEC, at the time that Defendants entered into or were trading pursuant to these plans, they were already aware of material adverse non-public information that negate the safe harbor that such a plan is supposed to provide, and, regardless, should have prevented their insider selling. For example, Defendants sold stock throughout 2006 and 2007 when they knew of the Company's relationship with DiscoCare, the illicit DiscoCare scheme, and that this scheme was driving the Spine revenue growth they were touting to the market.

# 2. Individual Defendants Attended Meetings and Received Reports

237. In addition, the Individual Defendants' scienter is evidenced by their receipt of internal reports and attendance at meetings. The Spine Regional Manager explained that Applegate, the Vice President of the Spine Division, would have met with Baker and Gluk. Moreover, this former employee stated:

there was always communication up the line to senior management. We did bimonthly reports by the field that would then be sent up the line to senior management. They were bi-weekly, kind of marketing reports – what was happening out in the field. We would get sales numbers from the company and then the regional managers like myself, Mike Denker or others would then send back feedback from the field about what was going on in the region. We would just give them kind of a sales and marketing update of trends and things that were happening – change we were making in the regions, people-hiring, firing – any important feedback from customers with regard to products, reimbursement etc.

These reports were called "bi-weekly marketing reports," and also included news about the marketplace and what the competitors were doing. This witness noted that his reports would go to Mike Moehring who was his director of sales and that he would then forward them up to senior

management. Moreover, senior management would send reports on a bi-weekly basis summarizing what was going on in the Company. This was confirmed by the Business Intelligence Analyst,<sup>67</sup> who stated that the heads of the business units would get weekly performance reports, illustrating budget versus actual for each territory manager and distributor. They also received monthly shipment detail reports, which illustrated how many units and dollars were shipped by month.

238. In addition, the Spine Marketing Assistant explained<sup>68</sup> that the Company held monthly staff meeting in the cafeteria. This witness recalled that at the Company's staff meeting in the cafeteria in the end of 2006, Defendant Baker spoke about the upcoming annual report and company performance. The Spine Marketing Assistant explained that Defendant Baker told the attendees that there were a lot of stories circulating to the effect that the Company was not doing well and that their numbers would be dropping. He advised them not to worry because the numbers would be coming right back up almost immediately. "He made it sound like he had the investors told that we were going to report significantly low numbers the next week, and that the reality is that we're going to be reporting amazing numbers next week. It sounded strange, why would he announce something like that to the company." Moreover, it evidences Baker's knowledge as to the effect that DiscoCare was having on the Company's Spine revenues in the last quarter of 2006.

239. Defendant Baker's attendance at the Company's meetings was confirmed by the Business Intelligence Analyst. In particular, this witness stated that at a Company meeting in Sunnyvale this year, around the time the news broke regarding the investigation of DiscoCare,

The former business intelligence analyst was employed with the Company from April 2005 until around the beginning of October 2008 ("Business Intelligence Analyst"). This witness reported sales numbers.

The former marketing assistant with the Spine Division of ArthroCare was employed with the Company from October 2005 through September 2007 in Sunnyvale, California ("Spine Marketing Assistant").

Defendant Baker stated that there was nothing wrong with what the Company was doing, that people should not believe what was being written, and that it was all a conspiracy by the short sellers writing articles to drive the price of the stock down.

### 3. Individual Defendants Undertook Due Diligence

240. As detailed above in ¶76, the Company undertook "extensive due diligence" of DiscoCare in the course of the Company's acquisition. Indeed, Baker told the market that the Company undertook additional due diligence focused on the false and misleading information underpinning stories in the marketplace. *Id.* Further, he stated that the "entire DiscoCare program has been carefully vetted and subjected to extensive legal and regulatory review." *Id.* Through these statements, Defendants undertook an affirmative obligation to the market to thoroughly investigate DiscoCare and its operations, and report material findings to the market. Defendants' failure to uncover the illicit DiscoCare scheme discussed herein through the course of due diligence and extensive legal and regulatory review, was at best severely reckless, if not entirely intentional.

#### 4. The Individual Defendants Received Enormous Bonuses

241. The Individual Defendants were strongly motivated to misrepresent ArthroCare's financial results because of the potential to receive enormous cash bonuses and stock option grants. According to the Company's proxy statement filed on April 29, 2008, the Company's "Compensation Committee believes that compensation paid to executive officers should be closely aligned with the performance of the Company on both a short-term and long-term basis, linked to specific, measurable results intended to increase the value of the Company, and that such compensation should assist us in attracting and retaining key executives critical to its long-term success." In addition, the Company's executive compensation program consists of cash-based compensation, which includes salaries, and bonuses consisting of cash and equity-based compensation in the form of stock option grants.

- 242. As detailed in the April 29, 2008 proxy, under the 2007 Executive Bonus Plan, all NEOS except the CEO, are eligible to receive a cash bonus equal to 60% of their base salary dependent on achievement of specific financial objectives tied to the annual Board approved operating plan. As CEO, Defendant Baker was eligible to receive a total bonus of 100% of his base salary under this plan, which is paid 75% in cash and 25% in RSUs. The actual bonus awarded under the plan depended on the level of achievement attained by the Company "as it relates to the Company's total net revenue and EBITDAC (earnings before interest, tax, depreciation, amortization, and non-cash equity compensation) goals as set forth in the Company's Board-approved operating budget for the applicable period." In addition, according to the Company's proxy filed on April 29, 2008, the Defendants also received long-term equity incentive awards which are among other things "closely tied to the Company's prior fiscal year performance . . . . ."
- 243. Due to Defendants' fraud as detailed herein, among other things, the Company's revenues were materially overstated during the Class Period. Consequently, in 2006, Defendant Baker received an annual salary of \$442,504 and a bonus of \$283,500. In 2007, Defendant Baker received a salary of \$466,807 and a bonus of \$341,923. Likewise, in 2006, Defendant Gluk received a salary of \$227,205 and a bonus of \$133,270. In 2007, Defendant Gluk received a salary of \$252,313 and a bonus of \$148,475. Defendants also received incentive stock and options grants which allowed them to enrich themselves at the expense of shareholders. Had Defendants Baker and Gluk reported the Company's financial results as restated, they would not have received this compensation. Since Defendants' compensation was tied to the Company's revenues and fiscal year performance, they were motivated to falsify key financial figures to obtain their incentive compensation.

### 5. ArthroCare's Restatements Establish Scienter

- 244. As indicated in ¶87, the fact that ArthroCare announced the restatement of its previous financial statements is an admission that: (i) the financial results originally issued during the Class Period and its public statements regarding those results were materially false and misleading; and (ii) the financial statements reported during the Class Period were incorrect based on information available to the Defendants at the time the results were originally reported.
- 245. The restatement of previously issued public financial statements is a serious and meaningful event. The accounting rules governing correction of errors or fraud in previously issued financial statements do not allow a registrant any discretion or election in deciding whether or not to retroactively restate the previous financial statements. GAAP only permits (and requires) restatements of previously issued financial statements to correct "errors," resulting from either: a) mathematical mistakes, mistakes in the application of GAAP or *oversight or misuse of facts that existed at the time the financial statements were prepared*; or b) a change in accounting principle or a change in the reporting entity. *See* SFAS No. 154, *Accounting Changes and Error Corrections*, "Summary," ¶2, 4-10, 23-26.
- 246. In this case, ArthroCare has admitted that its restatement was done solely to correct "errors," and *not* to change accounting principles or the reporting entity. Additionally, as alleged herein, it is clear that the type of "error" correction contained in the announced restatement at issue was also not due to a simple mathematical error, honest misapplication of an accounting standard or oversight; *rather, it was due to intentional misuse of the facts that were known at the time the previous financial statements were disseminated to the public*. The announced restatements at issue in this case contain at least the following indicators of knowledge by Defendants:
- (a) The type of restatement (misuse of the facts) The restatement at issue was not due to simple mathematical error or honest misapplication of an accounting standard or

oversight. It was the result of setting up or supporting affiliated entities to circumvent GAAP revenue recognition criteria and recording premature and inflated revenues on sales of experimental surgical devices that otherwise would have resulted in delayed, decreased, and/or no revenue recognition at all. As alleged herein, ArthroCare knew the sales involving the affiliated entities resulted in revenue recognition that was in violation of GAAP. Despite this knowledge, ArthroCare refused to make the required adjustments to correct the financial statements because they would have significantly impacted reported revenue and net income, adversely affected the stock price, and jeopardized its position as an attractive acquisition target;

- (b) The duration over which the improper accounting was perpetrated as more fully detailed herein, this is not a case of an honest mistake or oversight during a single quarter or even a single year that was realized and corrected on a good faith basis. ArthroCare restated six quarters of financial statements to correct fraudulent accounting, and only after the accounting improprieties could no longer be concealed;
- (c) *The magnitude or size of the restatement* This restatement was material. While, overall, for these three fiscal years, ArthroCare overstated its net income by at least 5% the overstatements of revenue and net income of losses during individual quarters is substantial;
- (d) The types of accounting gimmicks employed as detailed herein, the improper accounting corrected by this restatement did not occur as a result of good faith differences in accounting judgments, or interpretations of complicated, vague, or arcane accounting rules, and the Company does not claim otherwise. The accounting gimmicks used by ArthroCare are as old, simple and fundamental as they come namely, improper revenue recognition by failing to meet the fundamental criteria of revenue recognition, such as setting a fixed price, delivery of the goods and services, and the ability to collect payment from customers; and

- (e) Moreover, it is more than sheer coincidence that the aggregate purported "errors" in all of the restated quarters had the effect of inflating, not reducing, revenues and net income.
- 247. Finally, it is notable that the SEC has recently reiterated its position that, in its investigations of restated financial statements, it often finds that the persons responsible for the improper accounting acted with scienter:

[T]he Commission often seeks to enter into evidence restated financial statements, and the documentation behind those restatements, in its securities fraud enforcement actions in order, inter alia, to prove the falsity and materiality of the original financial statements [and] to demonstrate that persons responsible for the original misstatements acted with scienter... In re Sunbeam Sec. Litig., No. 98-8258-Civ.-Middlebrooks, SEC Amicus Curiae Brief (S.D. Fla. Jan. 31, 2002).

# VIII. PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE

- 248. The market for ArthroCare's publicly traded securities was open, well-developed and efficient at all times. As a result of these materially false and misleading statements and failures to disclose, ArthroCare's publicly traded securities traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired ArthroCare's publicly traded securities relying upon the integrity of the market price of those securities and the market information relating to ArthroCare, and have been damaged thereby.
- 249. At all relevant times, the market for ArthroCare's securities was an efficient market for the following reasons, among others:
- (a) ArthroCare's stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;
- (b) As a regulated issuer, ArthroCare regularly made public filings, including its Forms 10-K, 10-Q, and 8-K with the SEC and the NASDAQ;

- (c) ArthroCare regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and
- (d) ArthroCare was followed by several securities analysts employed by major brokerage firms such as Morgan Stanley, Bank of America Securities, Bear Stearns, Piper Jaffray & Co., and Needham & Co., who wrote research reports, which were distributed to the brokerage firms' sales force, and the public at large. Each of these reports was publicly available and entered the public marketplace.
- 250. As a result of the foregoing, the market for ArthroCare's securities promptly digested current information regarding ArthroCare from all publicly available sources and reflected such information in the prices of ArthroCare securities.
- 251. Under these circumstances, all purchasers of ArthroCare's securities during the Class Period suffered similar injury through their purchase of ArthroCare's securities at artificially inflated prices, and a presumption of reliance applies.
- 252. At the times they purchased or otherwise acquired ArthroCare's securities, Plaintiffs and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not reasonably have discovered those facts. As a result, the presumption of reliance applies. Plaintiffs will also rely, in part, upon the presumption of reliance established by a material omission.
- 253. In sum, Plaintiffs will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:
- (a) Defendants made public misrepresentations or failed to disclose facts during the Class Period;

- (b) The omissions and misrepresentations were material;
- (c) The Company's securities traded in an efficient market;
- (d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- (e) Plaintiffs and the other members of the Class purchased the Company's securities between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

## IX. LOSS CAUSATION

As detailed throughout and further herein, Defendants' fraudulent scheme artificially inflated ArthroCare's stock price by failing to disclose that: (a) since the end of 2005 and throughout the Class Period, ArthroCare had been actively engaged with DiscoCare in an illicit scheme to avoid traditional health insurance reimbursement hurdles and boost lagging Spine product sales; (b) ArthroCare and DiscoCare were wholly intertwined and joint venturers in the DiscoCare scheme; (c) as part of this scheme, ArthroCare encouraged its sales representatives to create a network of personal injury attorneys, physicians and facilities who would work together under the "DiscoCare Model" to aggressively push PDD procedures using ArthroCare SpineWands; (d) ArthroCare had created an assembly line approach to PDD procedures with its SpineWands that encouraged the performance of these procedures regardless of whether they were medically necessary; (e) ArthroCare coached physicians to upcode PDD procedures using its SpineWands to elevate charges associated with these procedures; (f) as a result of the DiscoCare Model, ArthroCare had dramatically raised the price of its SpineWands from approximately \$1,150 to \$7,500 for participants in the DiscoCare Model; (g) ArthroCare encouraged physicians in the DiscoCare network to base their charges on the available liability coverage from the paying insurer; (h) the DiscoCare Model was not an "algorithmic" approval process resulting in more insurer reimbursements but an

insurance scam by which Defendants circumvented the traditional insurance reimbursement model to bilk casualty insurers for inflated medical bills; (i) through support materials and training, ArthroCare encouraged its sales representatives to employ the illicit DiscoCare scheme in their territories; (j) the spike in Spine revenues and margins reported by the Company was not the result of improvements in reimbursement but rather the practice of its illicit scheme with DiscoCare; (k) ArthroCare's relationship with DiscoCare was at best that of a sales agent; (1) the Company's Class Period financial statements were materially misstated because ArthroCare improperly recognized revenues upon shipment of its SpineWands to DiscoCare in violation of GAAP; (m) ArthroCare engaged in the DiscoCare scheme to circumvent GAAP revenue recognition criteria and record premature and inflated revenues on sales of experimental surgical devices that otherwise would have resulted in either decreased and delayed revenue or no revenue at all; (n) the Company had engaged in premature revenue recognition on contingent sales to several distributors including SOTA, Boracchia, and Clinical Technology, Inc.; (o) the Company inflated revenue by failing to record offsets to revenue for commissions and marketing expenses paid to several entities including DiscoCare, SOTA, Boracchia, Clinical Technology, Inc., Arthroscopy & Medical Equipment International, Inc., and Frontier Medical, Inc.; (p) the DiscoCare acquisition was suspicious and had the effect of covering up the Company's true relationship with DiscoCare, the illicit DiscoCare scheme, and inflating ArthroCare's balance sheet; (q) ArthroCare's disclosure controls and procedures were ineffective; and (r) the Company's financial results during the Class Period were grossly overstated and were not GAAP compliant.

255. These false and misleading statements, individually and collectively, concealed ArthroCare's true financial circumstances and future business prospects, resulting in the stock being artificially inflated until, as indicated herein, the relevant truth about ArthroCare was revealed. While each of these misrepresentations was independently fraudulent, they were all motivated by

Defendants' desire to artificially inflate ArthroCare's stock price and the image of its future business prospects to give the market the false notion that ArthroCare's revenues were the result of increased reimbursement rates rather than the product of an illicit scheme with DiscoCare and company-wide channel stuffing. Defendants' false and misleading statements had the intended effect and causes, or were a substantial contributing cause of ArthroCare's stock trading at artificially inflated levels, reaching as high as \$65.70, throughout the Class Period.

256. The true picture of ArthroCare's relationship with DiscoCare, Defendants' illicit scheme, and the Company's true financial condition was not revealed to the market all at once. Rather, beginning on December 11, 2007, when ArthroCare's relationship with DiscoCare first came to light, the market began to ask questions, causing the truth to emerge slowly through a series of partial revelations which cast doubt on the veracity of the Company's Class Period statements, for example:

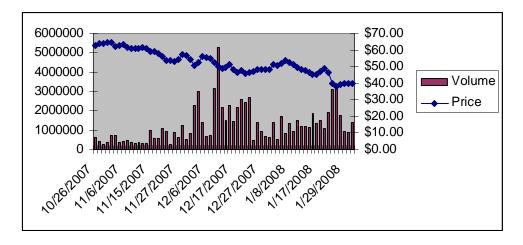
- **December 11, 2007 -** New York Post posted an article entitled "Surgical Device Maker's Growth Fueled Another Company." This article stated that ArthroCare's growth may be fueled by a Company by the name of DiscoCare and that the Company's relationship with DiscoCare is responsible for its stock price's rise. Moreover, the Post article questioned the close relationship between ArthroCare and DiscoCare, noting that Denker ran DiscoCare's daily sales operations.
- **December 14, 2007** ArthroCare issued a press release announcing that its Board of Directors had approved a repurchase of up to \$75 million in common stock and noting perceived inaccuracies in the December 11, 2007 New York Post article.
- **December 17, 2007** The Street Insider revealed that shares of ArthroCare stock were weaker "continuing last week's trend, due to concerns discussed in the New York Post of improprieties at the company's US Spine business related to the role of surgical device distributor DiscoCare." The article noted that ArthroCare was fighting these reports but that the Post is standing by its story.
- **December 20, 2007** www.seekingalpha.com published an article entitled "Red Flags at ArthroCare" which questioned ArthroCare's business practices, stating that they are "well beyond possible reimbursement issues, but could extend all the way to insurance

fraud." This article questioned why other medical device companies were having difficulty getting insurance reimbursement for their PDD products when ArthroCare was experiencing 95% growth in its spine business in one year alone. It also noted that ArthroCare had not mentioned DiscoCare in any of its public filings and was likely trying to distance itself from this entity. This article further shed light on the Palm Beach Lake Surgery Center, their high billing rates for PDD procedures, their involvement with the law firm of Steinger, Iscoe & Greene, and their connections to DiscoCare and ArthroCare. The article also mentioned DiscoCare's use of the "DiscoCare Model" and further questioned the Company's motives in conducting a share buyback.

- **December 27, 2007** www.seekingalpha.com published an article entitled "Lazard Capital Markets Confirms Concerns About ArthroCare." This article noted that Lazard Capital Markets was concerned about ArthroCare's reimbursement issues and the Company's aggressive share buyback. The article noted that ArthroCare had been losing market share and margins in its mainline divisions, and that this could be the motivation for the aggressive billing procedures in its spinal division. Moreover, the article questioned the DiscoCare/ArthroCare relationship, which it deemed "too close for comfort."
- **January 3, 2008** Defendants issued a press release announcing that ArthroCare will acquire DiscoCare. Defendants also host a conference call discussing the acquisition.
- January 8, 2008 www.seekingalpha.com published an article entitled "ArthroCare's acquisition of DiscoCare: Trying to Put the Genie Back in the Bottle." This article discussed ArthroCare's acquisition of DiscoCare, calling it a cover up of a "relationship predicated on fraud and deception." Moreover, the article noted that DiscoCare is really based out of the Palm Beach Lakes Surgery Center and noted that DiscoCare may be the billing arm of the Palm Beach Lakes Surgery Center, where billing is directed by Mark Izydore, a convicted felon.
- January 23, 2008 www.seekingalpha.com published an article entitled "Yet Another Secret Subsidiary Operating in the Shadows at ArthroCare." This article discussed Devise Reimbursement Services ("DRS"), an ArthroCare subsidiary, which appears to offer the same billing/coding facilitation for the Sports Medicine division that DiscoCare has for the Spine division. In addition, the article revealed that DRS's mailing address is ArthroCare's corporate headquarters and its officer is John Raffle, ArthroCare's VP of Strategic Business Units. This article also detailed how DRS and DiscoCare share the same fax number and how they are closely linked. Moreover, it

explained how ArthroCare encouraged upcoding and charged \$7,500 for a wand that cost \$1,200.

- 257. As a result of this series of partial revelations and the truth beginning to make its way into the marketplace, doubt was cast on the veracity of Defendants' prior public statements, and the artificial inflation began to slowly fall out of ArthroCare's stock price causing ArthroCare's stock to fall approximately 42% from a Class Period high of \$65.70 on November 1, 2007 to \$38.11 on January 25, 2008.
  - 258. This is evidenced in the chart below:



- 259. This stock drop would have been even more significant had the full truth regarding ArthroCare's business and financial condition been known. However, beginning in December of 2007, in the face of market concerns and uncertainty regarding ArthroCare's relationship with DiscoCare, Defendants continued to make false and misleading statements in order to maintain an appearance of legitimacy and artificially prop up ArthroCare's stock price, for example:
  - "The company also commented on a recent press report alleging that one of the company's reimbursement service providers may have engaged in inappropriate business practices, including an inaccurate allegation that the Massachusetts Attorney General's office was "looking into" ArthroCare's relationship with its service provider. This week, ArthroCare contacted the Massachusetts Attorney General's office and was informed that there was no such investigation. ArthroCare has carefully reviewed the article in question and found numerous material inaccuracies. The company

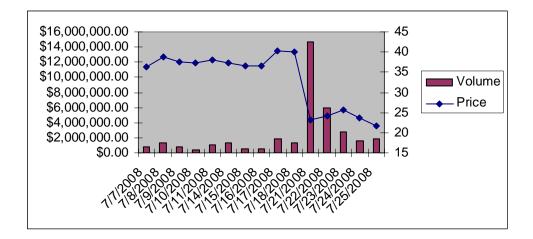
intends to contact the publisher to request a correction of the factual inaccuracies contained in the article." ¶69. Defendants forced the New York Post to withdraw the December 11, 2007 posting from view in order to keep the stock price artificially inflated.

- "In our acquisition due diligence, we found no evidence that PDD is being used overly aggressively or inappropriately by any of our customers who follow the DiscoCare treatment algorithm." ¶76.
- "[W]e did take extra time to go back and actually look at the facts behind some of these stories. And what we found was kind of what we just told you. That a lot of this stuff was either completely false or so misrepresented that it did not make any sense." ¶76.
- "[W]e don't code for physicians, full stop, and we don't code for facilities. I know there are some firms out there that do that, but DiscoCare is not one of the firms that does that. We don't code for surgeons. We don't code for facilities. We don't code for hospitals. And we don't tell them how to code." ¶78.
- "The DiscoCare model for ArthroCare's Plasma Disc Decompression procedure is actually a highly disciplined treatment algorithm that we believe is the key to successful authorizations and a significant contributor to excellent clinical outcomes." ¶75.
- "In the course of considering the acquisition of DiscoCare, we have not only conducted the normal extensive due diligence as we would with any acquisition, but we also completed additional due diligence work focused on the false and misleading information underpinning these stories." ¶76.
- "Like all of our marketing initiatives, the entire DiscoCare program has been carefully vetted and subjected to extensive legal and regulatory review." ¶76.
- "In addition to the false story about the Mass AG's office, there have also been rumors of numerous other investigations by various other authorities. All of these rumors have proven to be false, and it is interesting to note that one of the private research reports sponsored by the individuals and firms who were spreading these rumors actually confirmed that they could find no evidence of any other investigation." ¶145.

- forward to spending our time going forward talking the things that we actually are doing."
- "No. As far as we're concerned, the NASDAQ inquiry was very comprehensive and completely closes the issue. As to the shareholder lawsuit issue, there has actually been one shareholder lawsuit filed. There were about eight press releases done about it but there was one lawsuit filed. Often when you get one lawsuit, a bunch of other firms will do press releases hoping to find plaintiffs and, in fact, if you look at the lawsuit as it is written, companies always say that these things are without merit but in this case this really is without merit. The lawsuit basically on the face of it is, the things that it's alleging are factually inaccurate and it doesn't meet the standard for a lawsuit of this type. So we basically filed a motion to dismiss the lawsuit the day after it was filed and we believe that the lawsuit should, in fact, be dismissed and if for any reason it's not, then we'll simply go to trial and win on the merits. But if you read what's in the lawsuit -and it is public available -- and then you read our 10-K, you'll realize that what they're alleging is factually incorrect." ¶178.
- 260. These false and misleading statements and omissions, among others, had the intended effect of preventing the market from learning the full truth and keeping the Company's stock price artificially inflated throughout the Class Period. The true picture of ArthroCare's business, operations and finances were finally disclosed to the market on July 21, 2008, when the Company revealed its plans to restate its financial statements for the years ended December 31, 2006 and 2007, the quarters ended September 30, 2006, December 31, 2006, each of the quarters of 2007 and the quarter ended March 31, 2008, noting a required revenue adjustment resulting from a recommendation by management that revenue in these previously issued financial statements should be adjusted because: (1) the relationship between the Company and DiscoCare, Inc. during the periods being restated was a sales agent relationship, rather than that of a traditional distributor; and (2) the sales price of products sold to SOTA, Boracchia & Associates and Clinical Technology, Inc. cannot be considered fixed or determinable upon shipment by ArthroCare during the periods being restated. Moreover, the Company revealed that the restatement would correct errors identified by management regarding: (1) the classification to record as an offset to revenue for commissions paid

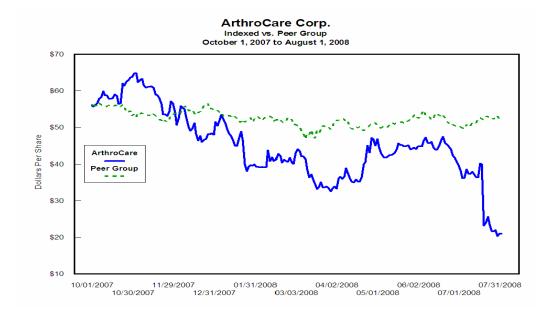
by ArthroCare to SOTA, Clinical Technology and Arthroscopy & Medical Equipment International, Inc. on products purchased directly by the distributor as principal and subsequently resold to third parties previously recorded as sales and marketing expense; (2) the classification to record as an offset to revenue of distribution and marketing fees paid to SOTA, Boracchia, Frontier Medical, Inc. and Clinical Technology previously recorded as sales and marketing expense that did not meet the criteria of EITF 01-9 "Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vender's Products)"; (3) the allocation of the purchase price for the DiscoCare acquisition on December 31, 2007 under FAS 141, "Business Combinations," as a result of the conclusion that DiscoCare was an agent prior to the acquisition, not a distributor; and (4) a foreign currency translation error in the fourth quarter of 2006 that was identified during management's conversion to the SAP enterprise financial reporting system.

- 261. When ArthroCare provided the market with these revelations of its true financial condition, it was an indication to the market that Defendants' prior Class Period statements were false and misleading. As a result of the information revealed to the market on July 21, 2008, the market cast doubt on the veracity of Defendants' prior statements causing ArthroCare's stock to drop approximately 42%, as it fell from \$40.03 on Friday, July 18, 2008 to close at \$23.21 on abnormally high trading volume.
- 262. The market's negative reactions to ArthroCare's revelations are demonstrated in the stock chart below:



- 263. The rapid decline in ArthroCare's stock price following the Company's July 21, 2008 disclosure was a direct and foreseeable consequence of the revelation of the falsity of Defendants' Class Period misrepresentations and omissions to the market. Thus, the revelation of truth at the close of the Class Period, as well as the resulting clear market reaction, support a reasonable inference that the market understood that ArthroCare's prior statements were false and misleading.
- 264. In sum, as the truth about Defendants' prior misrepresentations and concealments was revealed, the Company's stock price quickly sank, the artificial inflation came out of the stock, and Plaintiffs were damaged suffering true economic losses.
- 265. The decline in ArthroCare's stock price by approximately 65% from its Class Period high of \$65.70 to \$23.21 on July 21, 2008, was a direct result of the nature and extent of the revelations made to investors and the market, regarding ArthroCare's relationship with DiscoCare, its involvement in the illicit DiscoCare scheme, its practices of channel stuffing distributors such as Boracchia, SOTA and Clinical Technologies, and its various machinations of accounting fraud which led its revenues and financial statements to be materially overstated, that had been concealed or misrepresented by Defendants' scheme and misstatements.
- 266. The timing and magnitude of ArthroCare's stock price decline negates any inference that the losses suffered by Plaintiffs were caused by changed market conditions, macroeconomic or

industry factors or Company-specific facts unrelated to the Defendants' fraudulent conduct. This point is evidenced by the chart below that demonstrates the clear divergence of ArthroCare's stock price from its peer index<sup>69</sup> as the revelation of the truth became known to the market:



267. The economic loss, *i.e.*, damages, suffered by Plaintiffs were a direct and proximate result of Defendants' scheme and misrepresentations and omissions which artificially inflated ArthroCare's stock price, and the subsequent significant decline in the value of ArthroCare's stock when the truth concerning Defendants' prior misrepresentations and fraudulent conduct, entered the market place.

#### X. NO SAFE HARBOR

268. The federal statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking"

The peer group derived was derived from the Company's Proxy statement issued May 24, 2007 and is comprised of 18 leading medical technology companies: (ALGN, AMMD, ARRO, RMD, HAE, HOLX, COO, IMDC, MMSI, KYPH, CYTC, DJO, VMSI, WMGI, CNMD, MNT, DSCP, SYD).

statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of ArthroCare who knew that those statements were false when made. Moreover, to the extent that Defendants issued any disclosures designed to "warn" or "caution" investors of certain "risks," those disclosures were also false and misleading since they did not disclose that Defendants were actually engaging in the very actions about which they purportedly warned and/or had actual knowledge of material adverse facts undermining such disclosures.

## XI. PLAINTIFFS' CLASS ACTION ALLEGATIONS

269. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all those who purchased or otherwise acquired the publicly traded securities of ArthroCare between May 3, 2006 and July 18, 2008, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the Officers and Directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

270. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, ArthroCare's stock was actively traded on the NASDAQ. According to ArthroCare's SEC filings, as of shortly before the close of the Class Period, ArthroCare had more than 26 million shares outstanding. While the exact number of Class

members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by ArthroCare or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

- 271. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law complained of herein.
- 272. Plaintiffs will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests that are contrary or in conflict with the members of the Class they seek to represent.
- 273. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
- (a) whether the federal securities laws were violated by Defendants' acts as alleged herein;
- (b) whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
  - (c) whether Defendants' misrepresented material facts;
  - (d) whether the Exchange Act was violated by Defendants' acts alleged herein;
- (e) whether Defendants knew or were severely reckless in disregarding that the statements made by them were false and misleading;
- (f) whether the prices of ArthroCare's publicly traded securities were artificially inflated during the Class Period; and

- (g) the extent of damage sustained by Class members and the appropriate measure of damages.
- 274. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

## **COUNT I**

# FOR VIOLATIONS OF SECTION 10(B) OF THE EXCHANGE ACT AND RULE 10B-5 PROMULGATED THEREUNDER AGAINST ALL DEFENDANTS

- 275. Plaintiffs repeat and reallege each and every allegation set forth above as if fully set forth herein.
- 276. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein regarding ArthroCare's business, operations and management and the intrinsic value of ArthroCare's securities; (ii) artificially inflate and maintain the market price of ArthroCare's publicly traded securities; and (iii) cause Plaintiffs and other members of the Class to purchase ArthroCare's publicly traded securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.
- 277. Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for ArthroCare's securities in violation of Section 10(b) of the Exchange Act and Rule

- 10b-5. Defendants are sued as primary participants in the wrongful and illegal conduct charged herein.
- 278. In addition to the duties of full disclosure imposed on Defendants as a result of making affirmative statements and reports, or participation in the making of those statements and reports to the investing public, they had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of SEC Regulation (17 C.F.R. §210.01 *et seq.*) and S-K (17 C.F.R. §229.10 *et seq.*) and other SEC regulations, including accurate and truthful information about the Company's operations, financial condition and performance so that the market prices of the Company's publicly traded securities would be truthful, complete and accurate information.
- 279. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, practices, performances, operations and future prospects of ArthroCare as specified herein.
- 280. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of ArthroCare's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about ArthroCare and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of ArthroCare's securities during the Class Period.

- 281. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these Individual Defendants, by virtue of his responsibilities and activities as a senior officer and/or director of the Company was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) Defendants enjoyed significant personal contact and familiarity with the other Defendants and were advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's financial condition, performance, and operations at all relevant times; and (iv) Individual Defendants were aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.
- 282. Defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing ArthroCare's operating condition and business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and misstatements of the Company's business, operations and earnings throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.
- 283. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market prices of ArthroCare's securities

were artificially inflated during the Class Period. Unaware that market prices of ArthroCare's publicly traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class acquired ArthroCare's securities during the Class Period at artificially high prices and were damaged thereby.

- 284. At the time of said misrepresentations and omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known of the true performance, business practices, prospects and intrinsic value of ArthroCare, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their ArthroCare's securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.
- 285. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.
- 286. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

#### **COUNT II**

# FOR VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT AGAINST INDIVIDUAL DEFENDANTS

287. Plaintiffs repeat and reallege each and every allegation set forth above as though fully set forth herein.

288. The Individual Defendants acted as controlling persons of ArthroCare within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

289. In particular, each of these Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

290. As set forth above, ArthroCare and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

#### PRAYER FOR RELIEF

**WHEREFORE**, Plaintiffs, on their own behalf and on behalf of the Class, pray for relief and judgment, as follows:

- A. Declaring that this action may be maintained as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein;
- **B.** Awarding compensatory damages in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;
- C. Awarding Plaintiffs and the Class pre-judgment and post-judgment interest, as well as their reasonable costs and expenses, attorneys' and experts' witness fees incurred in this action; and
- **D.** Such other and further relief as the Court may deem just and proper.

# XII. JURY TRIAL DEMANDED

DATED: October 17, 2008

Plaintiffs hereby demand a trial by jury.

RUDMAN & ROBBINS LLP	
s/JACK REISE	
JACK REISE	

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Lead Counsel

# **CERTIFICATE OF SERVICE**

I hereby certify that on October 17, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF. I also certify that the foregoing document is being served this day on all counsel of record or *pro se* parties either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronically Notices of Electronic Filing.

s/JACK REISE JACK REISE

# EXHIBIT A

IN THE CIRCUIT COURT OF THE 15TH JUDICIAL CIRCUIT IN AND FOR MIAMI PALM BEACH COUNTY, FLORIDA CASE NO. 50 2007 CA004357XXXXMB AJ GERDA SILIEN, Plaintiff, ARMCHEM INTERNATIONAL CORPOORATION, a Florida corporation and ALFREDO ALEJANDRO PEREZ, Defendant. DEPOSITION OF JACQUELINE BROWN Wednesday, May 14, 2008 10:10 - 11:50 a.m. 44 West Flagler Street Suite 1200 Miami, Florida 33130 Reported By: Rick E. Levy, RPR, FPR
Notary Public, State of Florida
Network Reporting Corporation
Phone: 888.358.8188
305.358.8188 

1 APPEARANCES:

2 On behalf of the Plaintiff:

051408Brown 12 was a difference between the two. So you being in the business I guess and 13 14 you were already working down here in Miami Dade 15 County; right? 16 Yes, in pharmaceutical sales. Α 17 So you knew doctors down here? 0 18 Α Yes. 19 Q You're kind of involved in the medical community as part of your career? 20 21 Α Yes. 22 You called on some of those doctors to Q 23 ask them about Arthrocare? 24 Α Uh-hum. 25 Yes? Q

1 A Yes.

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Q And they told you about Arthrocare but

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3 you said that you learned that they were talking

4 about the sports medicine division?

5 A After I had already accepted the

6 position.

7 Q How did you learn that the doctors that

8 you were asking about Arthrocare were talking

9 about the sports medicine division as opposed to

10 another division like the spine division?

11 A That was after I accepted the position

12 when I called on my spine surgeons they said oh,

13 you should have taken the sports medicine side.

14 Q Did they tell you why?

15 A Yes, because the product was very

16 difficult to sell.

13

- 17 Q When you say the product are you talking
- 18 about the Arthrocare Spinewand?
- 19 A Yes.
- 20 Q Did they say why the product was
- 21 difficult to sell?
- 22 A Insurances considered it just a -- I
- 23 can't think of the exact word but it has not been
- 24 medically proven.
- 25 Q Approximately how many spine surgeons

1 told you that?

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- 2 A Two spine surgeons told me that.
- 3 Q Do you remember who they were?
- 4 A Dr. Jonathan Hyde.
- 5 Q Who else?
- 6 A And doctor -- also -- he's not really a
- 7 spine surgeon but he does spine, orthopedic spine.
- 8 The other one is Dr. Dennis Zaslow.
- 9 Q Did they tell you anything else about
- 10 Arthrocare, the SpineWand or the procedure?
- 11 A Well, I know Dr. Zaslow did use the
- 12 procedure. Dr. Jonathan Hyde did not.
- 13 Q Now, Hyde is located in Dade County?
- 14 A Yes. Very well respected spine surgeon.
- 15 One of the top spine surgeons.
- 16 Q And Zaslow is not -- is he located --
- 17 where is he located?
- 18 A He is located here in Coral Gables.
- 19 Florida.
- 20 Q Then he has a Broward County office too?

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- 1 Q Where did you interview, in Austin?
- 2 A No, here in Miami.
- 3 · Q Who interviewed you?
- 4 A Chris Carew and Trey Bawman.
- 5 Q What did they tell you about the
- 6 position and the interview?
- 7 A Really that it was a sales position, a
- 8 medical device position. To call on doctors to
- 9 get them to use the SpineWand for I guess
- 10 decompression.
- 11 Q Up until that point you hadn't had
- 12 medical device experience; correct?
- 13 A Correct.
- 14 Q What else did they tell you about what
- 15 you would be doing or how you would be doing it at
- 16 the time of the interview?
- 17 A No, just as a regular sales position, go
- 18 out and make calls, see if you can get them to use
- 19 the product for the doctors, that's it. Basically
- 20 cold calling accounts.
- 21 Q Did they tell you why the position was
- 22 being created down here?
- 23 A They said yes, because the business --
- 24 there was so much business for Jackie Marsh's
- 25 territory they needed to add one for Miami because

1 she wasn't able to cover the Miami territory.

2 Q They told you she was too busy?

- 3 A Right.
- 4 Q Did they ever suggest to you that you
- 5 meet her to see how she goes about doing her job?
- 6 A Yes, I had to spend one day with her.
- 7 Q That was early on in your employment I
- 8 take it?
- 9 A Correct.
- 10 Q And where did you do that?
- 11 A I went to Palm Beach Lakes Surgery
- 12 Center.
- 13 Q How was that arranged?
- 14 A I was to meet her up there to observe
- 15 cases.
- 16 Q So did you follow her around for a whole
- 17 day?
- 18 A No, actually we went there just to
- 19 observe cases and she left and left me there. So
- 20 I was only really a half day. She never showed
- 21 and she was supposed to work with me a second day
- 22 but she never showed either for the second day.
- 23 That was all my training.
- 24 Q Lucky you. You went to the Palm Beach
- 25 Lakes Surgical Center to observe some cases;

1 correct?

- 2 A Yes.
- 3 Q Your understanding when you went up
- 4 there is you were going to follow her around the
- 5 whole day but she didn't really complete that part
- 6 of it?
- 7 A Exactly.

Page 14

17

**17** A. Yes. 18 And you watched? Q 19 Α Right. 20 Did another doctor come in and do 21 something after she had done something? 22 Α Yes. 23 That's the one you don't know who it is 24 but another doctor did come in? 25 Α Correct.

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that.

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1 Q Just from your observation what did that 2 doctor do after Dr. Biceline was done with what 3 she was doing? 4 Α Just placed the wand into a spinal 5 needle. 6 Q How long did that take that doctor? Honestly I don't remember. 7 Α 8 Do you know how long the one whole 9 procedure with Dr. Biceline and the other doctor 10 took? 11 Α Honestly I don't remember. It was so 12 long ago. I don't know. It would be based on 13 doctor's skill level. I don't remember. Did Dr. Biceline do anything after the 14 other doctor came in and did what he was going to 16 do or did she leave and just stand back or what?

Not that I'm aware of. I think she

stood back I believe because there was other

procedures after I think but I can't be clear on

21	051408Brown Q Did you meet anybody else at the surgery		
22	center when you were there that day?		
23	A That day.		
24	Q You saw Jackie Marsh and you know you		
25	saw Dr. Biceline. You saw		
1	A I saw Michael Denker.		
2	Q Michael Denker?		
3	A That's it.		
4	Q Do you remember meeting anybody else?		
5	A There were a few people in the office		
6	but I don't remember meeting any of those people		
7	7 in the office.		
8	Q Was that the only time that you ever		
9	went to the Palm Beach Lakes Surgical Center?		
10	A I went there actually once before. I		
11	remember when I was interviewing I went up there		
12	one day. That was it.		
13	Q What did you do the time before when you		
14	went there for the interview?		
15	A I actually had to meet with Mike Denker.		
16	Q So as part of the interview process you		
17	had to meet Mr. Denker in addition to the separate		
18	interview that you had with the two other		
19	gentlemen?		
20	A Right, I just remembered that.		
21	Q So when you went up to the Palm Beach		
22	you met Mr. Denker first?		
23	A No.		
24	Q You met the other two first?		
25	A Correct.		
	Page 18		

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- 1 Then you met Mr. Denker? Q Correct. 2 Α After you got the job that's when you're 3 Q talking about going up with Jackie Marsh to watch 4 5 the procedure? Α Correct. 6 Was there anybody else other than those 7 Q 8 three gentlemen that you interviewed with prior to 9 getting the job? Α No. 10 All right, you met with Mr. Denker at 11 12 the Palm Beach Lakes Surgical Center? 13 Α Correct. What was his position? 14 Q 15 I was told that he was the -- one of the national sales managers for Arthrocare. I don't 16 remember his title actually. Maybe it wasn't --17 maybe -- I don't remember his actual title to tell 18 you the truth. 19 20 Did he meet with you in an office at the 21 surgery center? 22 Α Yes. 23 Does it appear to be his office? Q 24 Α It was more of a conference room.
- 1 he came up there just to see you or what?
- 2 A I have no idea.

Q

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Page 19

Do you know if he was typically there or

051408Brown What did he tell you about the position 3 4 that you were interviewing for? 5 No, that it was a sales position, 6 calling on doctors to sell the SpineWand. 7 Did he tell you anything else about the 8 position that you can recall? 9 No. I know he had talked something 10 about the DiscoCare model but of course at that 11 time I didn't understand what that was as today I 12 really don't understand what it is. 13 But he mentioned the DiscoCare model to 14 you? 15 Α Um-hum. 16 That's a yes? Q 17 Α Yes. 18 Q At that time did he give you any 19 description of what the DiscoCare model entailed? 20 Α No. 21 Did he tell you that you would need to 22 implement the DiscoCare model as a part of your 23 job to sell the device though? 24 No, I didn't have to in my position at 25 that time. I don't know if things have changed

1 with the company but at that time I worked there.

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Q I want to see if I can understand

- 3 correctly though. You interviewed with Mr. Denker
- 4 about the position for Miami Dade County to sell
- 5 the SpineWand?

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- 6 A I actually already received the
- 7 position. They wanted me to meet with him. So it Page 20

- 8 wasn't really an official interview. I had
- 9 already received the position. They wanted me to
- 10 meet him as well.
- 11 Q Thank you for clarifying that. I
- 12 thought it was an interview. To me --
- 13 A Interview process. I already accepted
- 14 the position. They wanted me to go there and meet
- 15 with him as well.
- 16 Q So scratch the part about the interview
- 17 but they wanted you to go meet with him and so you
- 18 did?

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- 19 A Uh-hum.
- 20 Q Correct?
- 21 A Yes.
- 22 Q And then in talking with him he talked
- 23 to you about selling the SpineWand?
- 24 A Correct.
- 25 Q Was he of the same understanding you
- 1 were going to have Miami Dade County and Jackie

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- 2 Marsh was going to retain everything north of
- 3 Miami Dade County in Florida?
- 4 A Yes.
- 5 Q Then he mentioned to you the DiscoCare
- 6 model at some point?
- 7 A Yes.
- 8 Q And in what context, what else do you
- 9 recall him mentioning about that?
- 10 A New third party billing they had
- 11 implemented at that particular surgery center they

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051408Brown The hospitals just said they didn't like 21 22 to use third party billing. They wouldn't go 23 through third party billing. That's all I know. 24 Q If I understand correctly then the 25 hospitals or whoever down in Dade County was not 1 going to agree at least or to participate in 2 having some other party billing and medical device 3 they used? 4 Α Correct. 5 Q So in other words down in Dade County 6 people wanted to buy the device and roll it into 7 their fee or how were they saying this they were 8 going to bill it? 9 I would charge the company directly which is how I billed for everything. You charge 10 the company directly. 11 So in other words, down in Dade County 12 13 Arthrocare would directly sell to a hospital or 14 some kind of provider and that provider would get 15 a bill from Arthrocare for certain amount? 16 Α Correct. 17 Do you know anything about how they 18 would turn around and whether they would bill it or roll it into their fee or what? 19 No, I don't know what you're talking 20 21 about. Let me clarify something. I didn't have 22 any business down here in Dade County for the few 23 months I worked. You just stood and observed 24 cases that already had bills so I didn't have any

business going through hospitals.

Page 24

I went to

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- 1 hospitals and talked to them to set up when you
- 2 start a new position you go in, you give them your
- 3 information, fill forms out, your card and all of
- 4 that so the company you find out what the rules
- 5 and policies are of the company. That's how I
- 6 know that information and I never did any surgery
- 7 cases in any hospitals.
- 8 Q That kind of cut a little bit out?
- 9 A Yes.
- 10 Q Basically you didn't complete any sales
- 11 of SpineWand down here?
- 12 A No, nothing.
- 13 Q No, is that correct?
- 14 A I didn't have any cases down here.
- 15 Q But your understanding was going to be
- 16 that the way it was going to happen is you were
- 17 going to sell from Arthrocare to a hospital or a
- 18 surgeon and they were going to pay Arthrocare a
- 19 fee for the SpineWand?
- 20 A Yes.
- 21 Q Did you ever propose to any hospitals,
- 22 physicians or surgery centers to do third party
- 23 billing and then they rejected it?
- 24 A No, I didn't propose.
- 25 Q Did they tell you in advance they

- 1 wouldn't do it or that the only way they would do
- 2 it is a direct bill?

- 3 A Yes, I said -- I showed them these are
- 4 the forms I received from the company because I
- 5 did not know -- this is what I was received being
- 6 new to spine device or device sales they gave me
- 7 those forms you could use and we cannot use the
- 8 third party billing I said fine. Well, we just do
- 9 this do everything direct. That's how it was set
- 10 up.
- 11 Q So then when you would go to hospitals,
- 12 surgeons or surgery centers in Dade County and
- 13 talk to them or try to make a sales call you would
- 14 present certain forms to them that entailed third
- 15 party billing and you were uniformly told they
- 16 weren't going to do that; is that fair to say?
- 17 They weren't going to participate in third party
- 18 billing?

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- 19 A I didn't know when I first started when
- 20 I handed everything out I didn't know they were
- 21 not going to start that until after.
- 22 Q Ultimately you learned that nobody that
- 23 you tried to sell to in Dade County was going to

- 24 agree to the third party billing system?
- 25 A Exactly. There was no one that did
- 1 participate in that.
- 2 Q So in Dade County nobody agreed to
- 3 pay -- participate in the third party billing
- 4 system known as the DiscoCare model?
- 5 A Correct.
- 6 Q So consequently you were not going to be
- 7 able to sell anything in that fashion? Page 26

- 8 A No, actually no thinking back I may have
- 9 had two surgery cases that's all but of those
- 10 cases they were not DiscoCare cases.
- 11 Q They were direct bills?
- 12 A They were direct only.
- 13 Q And what were -- when you would -- those
- 14 cases, you would directly sell an Arthrocare
- 15 SpineWand to a medical provider; correct, you
- 16 would sell --
- 17 A No, you have the equipment and that gets
- 18 sold to the hospital. The hospital purchased that
- 19 equipment for the doctor and that gets sent
- 20 through however it is.
- 21 Q So then you would sell an Arthrocare
- 22 SpineWand to a hospital; right?
- 23 A Yes.
- 24 Q Then the hospital would receive a bill
- 25 from Arthrocare?

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- 1 A Correct.
- Q Would it be generated out of your office

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- 3 or Texas or where?
- 4 A I believe it was out of Texas.
- 5 Q You were selling this so you know I
- 6 assume how much they were going to cost when they
- 7 were direct billed by Arthrocare?
- 8 A Yes.
- 9 Q How much were they going to cost when
- 10 they were direct billed by Arthrocare?
- 11 A I believe \$1,400 I think.

Do you know anything about how the

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13 hospitals whether -- how the hospitals would bill 14 their procedures? 15 Α No. 16 Q So you only know the part about you 17 would sell a SpineWand to a hospital, they would 18 be charged \$1,400 by Arthrocare? 19 Right. That's all I know. I believe 20 that was charged for that. I don't know. 21 Well, it was your understanding that it 22 was about \$1,400? 23 Α Yes. 24 Q Did you ever talk to Chris Carew about 25 the Discocare model? 1 Α Yes. 2 Q Did you ever talk to Trey Bawman about 3 the Discocare model? 4 No, briefly, no. He tried to explain it 5 to me but he didn't explain anything. Actually Chris Carew could not explain it to me either. I 6 was never trained on the procedure. I was never 7 8 trained on the Discocare model. 9 You did observe a procedure or a couple 10 procedures up at the surgery center; right? 11 Α Yes. 12 Q And was that the only time you ever 13 observed any procedures? 14 Α No, I observed procedures with 15 Dr. Dennis Zaslow. 16 Q Did you ever sell him a SpineWand?

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1 A No.

- 2 Q Did Arthrocare ever give you any
- 3 materials for you to review that would give you
- 4 any ideas on how to go about selling the
- 5 SpineWand?
- 6 A There was information on their internet
- 7 but that is all for you to pull down information
- 8 on how to sell.
- 9 Q Now, when you say on the internet
- 10 there's the internet --
- 11 A The company information, their system.
- 12 Their internet system.
- 13 Q So then there's the internet that is out
- 14 there for everybody to see, company can have a web
- 15 site and you or I without any kind of password
- 16 would look up their Web site. Did Arthrocare have
- 17 more of an internal intranet however?
- 18 A I believe everything was publicly out
- 19 there that they had. As far as I recall.
- 20 Q Did you ever get any kind of log in or
- 21 password or I.D. to get into anything electronic
- 22 with Arthrocare?
- 23 A Yes, I had a company laptop.
- 24 Q Did you have any kind of an I.D. or
- 25 password that would get you on to the Arthrocare

1 computer network system?

2 A Yes.

051408Brown 3 Q What was that called, that internal system that you could access with a password? 4 5 Α I have no idea. What kind of information did you see on 6 Q 7 it? 8 They had of course information about --9 there's DiscoCare forms that you could find. 10 There was information about spine. I guess the 11 model of the bones, anatomy. I don't remember. That's about it. I don't remember what else was 12 13 on there. 14 Q So if you would log in and use a password you would have access to some DiscoCare 15 forms and whatnot, none of which you were ever 16 17 able to ultimately utilize though? 18 Α Correct. 19 That's correct; is that correct? Q 20 Α Yes. 21 Do you know if the forms described in 22 any way any kind of process for this DiscoCare 23 model? 24 Α They had processes on there I guess how 25 to go about filling forms out and who to contact

1 at DiscoCare but as far as knowing exactly how to

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2 do that, no.

D

- 3 Q They had information on there that
- 4 pertained to DiscoCare billing model?
- 5 A Correct.
- 6 Q Which you ultimately were never able to
- 7 successfully use?

- 8 A Right.
- 9 Q What did Mr. Carew tell you about the
- 10 DiscoCare model?
- 11 A He told me he was new to this division
- 12 and he didn't really quite understand it himself.
- 13 Q Was that it?
- 14 A That was it. We never discussed it
- 15 because again it was something I was not using in
- 16 my territory.
- 17 Q What about Mr. Bawman, did he ever
- 18 discuss the Discocare model with you?
- 19 A No. Never discussed it.
- 20 Q Did you ever discuss it with anybody
- 21 else at Arthrocare?
- 22 A No.
- 23 Q Not Mr. Applegate?
- 24 A No, never talked to him.
- 25 Q You never talked to him period; is that

39

1 correct?

- 2 A No.
- 3 Q No, it's not correct?
- 4 A No, I have never talked to him. I think
- 5 he called me to say welcome aboard when I first
- 6 started and that was the only time I spoke with
- 7 him.
- 8 Q Then was it your understanding when you
- 9 talked to Mr. Denker that he was an Arthrocare
- 10 employee?
- 11 A Yes.

Do you know whether or not he was a

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Q

DiscoCare employee? 13 14 I don't know what his role was. 15 didn't figure that out while I worked there. I know he participated with Discocare but he was an 16 17 Arthrocare employee. 18 Did he indicate to you that he had 19 something to do with implementing the DiscoCare 20 model up there at that surgery center in Palm 21 Beach? 22 Yes. Α 23 Q On behalf of Arthrocare? 24 Α I quess. 25 Well, you knew him to be an Arthrocare Q employee? 1 2 Α Right. You don't know one way or another 3 Q whether he had any kind of employment relationship 4 5 or contract relationship with DiscoCare? 6 Α No. 7 So if he did that's just unknown to you? Q 8 Right. Α 9 But you did ascertain from your Q 10 discussion with him that he was in business even 11 if it was on behalf of Arthrocare implementing the 12 DiscoCare billing model for that Palm Beach Lakes Surgical Center; is that correct? 13 14 Α I guess. 15 Q Go ahead. 16 Α I don't understand what you're saying. Page 34

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- 17 exist while you were with Arthrocare?
- 18 A No.
- 19 Q Did anybody ever talk about a position
- 20 that addresses these things while you were there
- 21 or any element of it?
- 22 A No, but I know this was something they
- 23 called a blitz they wanted to do out in
- 24 California. Throughout different areas in the
- 25 United States, Texas, California and areas like

1

that.

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- Q What was the blitz to entail?
- 3 A They were to call on I guess attorney's
- 4 offices as looking here what that paper states to
- 5 try find business for that.
- 6 Q So while you were there the blitz did
- 7 not take place down here?
- 8 A No.
- 9 Q But while you were employed by
- 10 Arthrocare you heard about the blitz?
- 11 A Yes.
- 12 Q And you heard about the blitz from
- 13 Arthrocare?
- 14 A Right.
- 15 Q And that entailed calling on law firms?
- 16 A Correct. Working with law firms.
- 17 Q Working with law firms?
- 18 A Yes.
- 19 Q Who told you about the blitz that was
- 20 going to go on in some other regions?

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051408Brown 21 Chris Carew and Trey Bawman called me they were going to do the blitz. 22 What else did they tell you about the 23 Q blitz? 24 They wanted me to fly out to be a part 25 Α 1 of it in California and I went for one day and 2 left. I flew home. 3 Q How long were you supposed to be there? I think for the week. For the week and 4 that's it. 5 6 Q Why did you leave? I just told my boss this was not 7 8 something I wanted to do. 9 You were not comfortable being a medical device sales representative calling on personal 10 11 injury law firms? 12 Right, there was with one law firm they were working with at the time up there in **1**3 California. 14 15 And you were not comfortable with it? 16 Α No. Who did you talk to about your -- did 17 18 you just leave without explanation or did you tell somebody I'm not comfortable? 19 I told my boss I was not -- I didn't 20 want to participate in this. He was like -- he 21 22 agreed so that was that. 23 Q You're talking about Mr. Carew? 24 Α Correct. 25 Q Was he out there too?

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# EXHIBIT B

Clinical Policy Bulletin: Nucleoplasty

Number: 0602

# **Policy**

Aetna considers Nucleoplasty (also known as percutaneous radiofrequency thermomodulation or percutaneous plasma diskectomy) experimental and investigational for the percutaneous decompression of herniated vertebral discs, and for all other indications because there is inadequate evidence of the safety and effectiveness of this treatment method.

See also CPB 016 - Back Pain - Invasive Procedures.

# **Background**

Nucleoplasty (also known as percutaneous radiofrequency thermomodulation or percutaneous plasma diskectomy) is a percutaneous method of decompressing herniated vertebral discs that uses radiofrequency energy (Coblation (ArthroCare Corp., Sunnyvale, CA)) for ablating soft tissue, and thermal energy for coagulating soft tissue, combining both approaches for partial disc removal.

Coblation ablates tissue via a low-temperature, molecular dissociation process to create small channels within the disc. While monitoring the patient, a series of channels are created by advancing a catheter (Perc-D Coblation Channeling Wand) into the disc while ablating tissue. After stopping at a pre-determined depth, the catheter is slowly withdrawn. On withdrawal, the channels are thermally treated, producing a zone of thermal coagulation. The catheter is then rotated clockwise, and another channel is created. Approximately six channels are created, depending on the desired amount of tissue reduction. The Nucleoplasty procedure is performed on an outpatient basis under local anesthesia and fluoroscopic guidance, with the patient in a lateral or prone position.

Nucleoplasty is designed to avoid the substantial thermal injury risks of Intradiscal Electrothermal Annuloplasty (IDET), because Nucleoplasty produces lower temperatures within the disc annulus. Data from ArthroCare using cadaveric models shows that IDET generates substantially higher tissue temperatures within the nucleus and superior endplates of the

vertebral disc than the Nucleoplasty procedure. Increased temperatures play a detrimental role with respect to cartilagenous vertebral endplates and surrounding tissues.

ArthroCare, manufacturer of the Perc D Coblation Channeling Wand that is used to perform the Nucleoplasty procedure, has posted unpublished results of case reports and case series of the Nucleoplasty procedure on their website. However, there are no studies of the effectiveness of the Nucleoplasty procedure published in the peer-reviewed medical literature.

An assessment by the National Institute for Clinical Excellence (2004) concluded: "Current evidence on the safety and efficacy of percutaneous disc decompression using Coblation for lower back pain does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research.... The lack of data makes it difficult to draw conclusions regarding the efficacy of the procedure. The lack of long-term and comparative data also makes it difficult to distinguish between the treatment effect and the natural history of the disease, as well as determine whether the benefits of this procedure are sustained beyond 12 months."

An assessment by the Washington State Department of Labor and Industries (2004) found that no randomized trials have been conducted to study the efficacy of nucleoplasty. The assessment concluded that, because only case series studies have been conducted to examine the efficacy of this procedure, it is considered investigational.

Marin (2005) stated that Nucleoplasty is a promising minimally invasive technique for the treatment of symptoms associated with contained herniated disc. However, randomized controlled studies are required to know with more precision the role of this procedure. Cohen and colleagues (2005) ascertained determine the treatment outcomes of 16 consecutive patients with lumbar radicular pain secondary to a herniated disc who underwent Nucleoplasty as their primary therapy. These investigators concluded that Nucleoplasty is not an effective long-term treatment for lumbar radiculopathy, either alone or with IDET.

A technology assessment by the California Technology Assessment Forum (CTAF, 2002) concluded that Nucleoplasty percutaneous disc decompression does not meet CTAF's assessment criteria.

An assessment of radiofrequency techniques (nucleoplasty, percutaneous thermocoagulation, and electrothermal annuloplasty) by the <u>Institute for Clinical Effectiveness and Health Policy (Lopez, et al., 2005)</u> reached the following conclusions: "Radiofrequency techniques are new technologies and little information is published about them. The data come mostly from observational studies of poor-level evidence whose main limitation is lack of comparison against control groups treated using conventional strategies (analgesics and physical therapy). This limitation is particularly significant in pathologies such as low back pain which presents a high rate of spontaneous resolution. This makes it difficult to draw conclusions about the efficacy of the procedures and their mid and long term safety... The evidence currently available on the three techniques does not support the use of these procedures on routine basis beyond the research framework."

Marin (2005) stated that Nucleoplasty may be an effective minimally invasive technique for the treatment of symptoms associated with contained herniated disc. However, randomized controlled studies are needed to ascertain with more precision the role of this procedure.

Bhagia et al (2006) reported the short-term side effects and complications after percutaneous disc decompression utilizing Coblation technology (Nucleoplasty). Following institutional review board approval, consecutive patients who were to undergo percutaneous disc decompression using Nucleoplasty were prospectively enrolled. Patients were questioned preoperatively, post-operatively, and 24 hours, 72 hours, 1 week, and 2 weeks post-procedure by an independent reviewer regarding 17 possible symptom complications, which included bowel or bladder symptoms, muscle spasm, new pain, numbness/tingling or weakness, fevers/chills, rash/pruritis, headaches, nausea/vomiting, bleeding, and needle insertion site soreness. Statistical analysis was performed using Wilcoxon's signed-rank test. A total of 53 patients enrolled, of whom 4 patients dropped out. Two patients had increased symptoms and opted for surgery. Two patients could not be contacted. The most common side effects at 24 hours post-procedure was soreness at the needle insertion site (76 %), new numbness and tingling (26 %), increased intensity of pre-procedure back pain (15 %), and new areas of back pain (15 %). At 2 weeks, no patient had soreness at the needle insertion site or new areas of back pain; however, new numbness and tingling was present in 15 % of patients. Two patients (4 %) had increased intensity of pre-procedure back pain. There were statistically significant reductions in visual analog scale (VAS) score for back pain and leg pain (p < 0.05). The authors concluded that based on this preliminary data, Nucleoplasty seems to be associated with short-term increased pain at the needle insertion site and increased pre-procedure back pain and tingling numbness but without other side effects.

In a prospective, non-randomized, longitudinal, cohort study, Gerszten et al (2006) assessed pain, functioning, and quality of life (QOL) in patients with radicular leg and back pain who underwent Nucleoplasty-based percutaneous disc decompression. A total of 67 patients (mean age of 41 years) with primarily radicular pain due to a contained disc herniation underwent Nucleoplasty-based decompression in an outpatient setting. Patients completed the Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey, EuroQol 5D (EQ5D), and a VAS for pain pre-operatively, and at 3 and 6 months after surgery. Post-operative QOL differences were assessed using the Wilcoxon signed-rank test. A surgical probe, the Perc-DLE SpineWand, was placed percutaneously into the disc after application of a local anesthetic or induction of general anesthesia to remove part of the disc (i.e., a percutaneous discectomy). Nucleoplastytreated levels were L2 - L3 (one case), L3 - L4 (five cases), L4 - L5 (44 cases), and L5 - S1 (40 cases); there were 22 multiple treatment levels and 42 bilateral treatments. There were no infections or nerve root injuries associated with the procedure. Compared with pre-operative QOL, there was a statistically significant improvement in QOL at 3 months as measured using the SF-36 Physical Component Summary (PCS) scale (mean score improvement 4.4 [p = 0.014]), the EQ5D (mean score improvement 0.22 [p = 0.001]), and the VAS for pain (mean score improvement 0.13 [p = 0.021). Six-month results in 36 patients continued to reflect improvement as measured using the SF-36 PCS (mean score improvement 7.6 [p = 0.002]) and the EQ5D (mean score improvement 0.27 [p = 0.001]). The authors concluded that Nucleoplasty-based percutaneous disc decompression in patients with symptomatic contained disc herniations is safe and improves QOL as measured by the SF-36, EQ5D, and VAS for pain,

three generic QOL outcome instruments. Nucleoplasty is an effective minimally invasive surgical treatment alternative in patients with symptomatic contained disc herniations. They noted that further follow-up evaluation is underway to determine the durability of QOL improvement after Nucleoplasty.

The National Institute for Health and Clinical Excellence's guideline on percutaneous disc decompression using coblation for lower back pain (2006) stated that "[c]urrent evidence suggests that there are no major safety concerns associated with the use of percutaneous disc decompression using coblation for lower back pain. There is some evidence of short-term efficacy; however, this is not sufficient to support the use of this procedure without special arrangements for consent and for audit or research....Further research will be useful in reducing the current uncertainty, and clinicians are encouraged to collect long-term follow-up data". The guideline also stated that the Specialist Advisors expressed uncertainty regarding the efficacy of this procedure.

In a retrospective, non-randomized case series. Yakovlev et al (2007) assessed the effect of Nucleoplasty on pain and opioid use in improving functional activity in patients with radicular or axial low back pain secondary to contained herniated discs. A total of 22 patients who had undergone Nucleoplasty were included in the analysis. Patients were evaluated at 1, 3, 6, and 12 months post-operatively, and were asked to quantify their pain using a VAS ranging from 0 to 10. Patients were also surveyed in regards to their pain medication use, and functional status was quantified by a physical therapist who also used patient reports of ability to perform activities of daily living to assess status. Data were compared between baseline and at 1, 3, 6, and 12 months post-treatment. Reported pain and medication use were significantly decreased and functional status was improved at 1, 3, 6, and 12 months following Nucleoplasty (p values les than or equal to 0.0010 for all outcome measures at all time periods). There were no complications associated with the procedure and continued improvements were observed over time. The authors concluded that Nucleoplasty appears to be safe and effective; however, they noted that randomized, controlled studies are needed to further evaluate its long-term effectivenesss.

## **CPT Codes / HCPCS Codes / ICD-9 Codes**

CPT codes not covered for indications listed in the CPB:

62287

# HCPCS codes not covered for indications listed in the CPB:

S2348 Decompression procedure, percutaneous, of nucleus pulposus of

intervertebral disc, using radiofrequency energy, single or multiple levels,

lumbar

# ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

354.0 - 355.9	Mononeuritis of upper and lower limbs
722.0 - 722.93	Intervertebral disc disorders

723.4 Brachial neuritis or radiculitis, NOS

724.4 Thoracic or lumbosacral neuritis or radiculitis, unspecified

Neuralgia, neuritis, and radiculitis, unspecified

# The above policy is based on the following references:

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# EXHIBIT C



# NUCLEOPLASTY PERCUTANEOUS DISC DECOMPRESSION

## **ISSUE**

Blue Shield has received requests for coverage of nucleoplasty percutaneous disc decompression for herniated discs. The Medical Policy Committee on Quality and Technology is asked to review the published data regarding the efficacy and safety of this new technology in clinical practice.

# **CURRENT BLUE SHIELD POLICY**

Current Blue Shield policy (06/09/99) states that, "Percutaneous intradiscal radiofrequency thermocoagulation for low back pain is investigational and not eligible for coverage." Furthermore, Blue Shield policy (10/15/01) states that "percutaneous laser disc decompression is investigational and not eligible for coverage." Conservative measures and other surgical modalities are eligible for coverage.

## BACKGROUND

Low back pain is the most common cause of morbidity and chronic pain in the U.S.. Herniation of a lumbar disc is sometimes responsible. The incidence of disc herniation in the U.S. is approximately 1.7% (Choy, 1995b). The disc resembles a filled jelly donut, being composed of a series of firm, fibrous rings (annulus fibrosus) surrounding a soft, jelly-like core (nucleus pulposus). Herniation occurs when the nucleus material escapes through the annulus. Even in the absence of frank disc herniation, however, degeneration and bulging of the disc may itself be the source of the low back pain. There are nerve endings and fibers in the outer half of the annulus fibrosus (Houpt *et al*, 1996).

The usual treatment for a patient with a symptomatic, nonsequestered herniated nucleus pulposus first involves conservative measures, such as nonsteroidal anti-inflammatory drugs, physical therapy, muscle relaxants, selective nerve blocks, epidural steroids, and in some cases chiropractic care (Casper *et al*, 1996). Traditionally, further treatment for a disc herniation that has been unresponsive to conservative measures has involved either open laminectomy or discectomy. Patients often benefit from complete surgical removal of the intervertebral disc and vertebral fusion; measurable decrease in preoperative pain has been noted in >80% in various series (Lee *et al*, 1995).



## BACKGROUND, continued

Minimally invasive intradiscal techniques and percutaneous procedures have recently been employed as an alternative to conventional surgical methods. These have included chemonucleolysis, manual percutaneous discectomy, automated percutaneous discectomy, endoscopic posterolateral discectomy, and laparascopic discectomy and fusion, and percutaneous laser disc decompression (also known as laser discectomy) (Maroon *et al*, 1996; Fehlings, 1996).

# **Nucleoplasty Percutaneous Disc Decompression**

Nucleoplasty percutaneous disc decompression is a new, "minimally invasive" procedure to provide symptomatic relief of pain caused by a herniated intervertebral disc (Sanders, 2001). Nucleoplasty is performed in the outpatient setting under fluoroscopic guidance and local anesthesia. In nucleoplasty, the target tissue is the nucleus pulposus of the intervertebral disc (Sanders, 2001), the main constituent of which is water (Quigley, 1996).

In nucleoplasty, a multifunctional bipolar radiofrequency device is used to generate thermal energy (heat) to ablate (remove) or coagulate tissue. Thermal damage to nearby tissues is minimized since these effects are achieved at temperatures of approximately 40-70°C.

During the procedure, the patient is placed in the lateral position with the affected side up. After localization of the disc level, a thin gauge (18- to 20-gauge) needle with a stylet is introduced and placed percutaneously at the nucleus/annulus junction. A radiofrequency device (the Perc-D SpineWand™) is introduced through an introducer needle and advanced into the nucleus pulposus. Using the ablation mode, the device is advanced ("channeled") into the nucleus, stopping before reaching the anterior annular wall. Coagulation mode is then used while withdrawing the device. The same procedure is repeated six times within the disc. The needle is then removed and a bandage placed on the skin. The procedure takes between 20 and 30 minutes.

It is theorized that the change in the nucleus pulposus causes a decrease in intradiscal pressure which in turn allows the herniated material to retreat toward the center of the disc.



# Nucleoplasty Percutaneous Disc Decompression, continued

Proponents of nucleoplasty cite several potential advantages over open discectomy procedures: possibly reduced morbidity, less potential for perineural scarring, less intraoperative blood loss, fewer complications of epidural fibrosis, transverse myelitis or disc space infection, reduced patient recovery times, and a faster return to normal activity. In addition, the procedure can be repeated, and it does not preclude future surgical treatment.

The procedure has only applied to lumbar disc herniations.

# **TECHNOLOGY ASSESSMENT (TA)**

#### TA Criterion 1

ArthroCare Corporation, Sunnyvale, CA received FDA 510K clearance on August 17, 2000 as "substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act". The ArthroCare System 2000 is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurosurgical procedures.

## TA Criteria 2 and 3

There are no peer-reviewed published studies concerning nucleoplasty. Specifically, no randomized, concurrently controlled, blinded trials comparing nucleoplasty outcomes with conventional conservative measures or open discectomy or laminectomy have been published.

The only available studies of nucleoplasty are summarized in abstracts, several of which are animal studies (Chen *et al*, 2001a; Chen *et al*, 2001b) or human cadaver studies (Chen *et al*, 2001c; Yetkinler *et al*, 2001); three abstracts summarize case series of nucleoplasty in humans (Chen *et al*, 2001d; Sharps, 2001; Singh, 2001).



## TA Criteria 2 and 3, continued

Patients included in the abstracts have included those with axial and/or radicular symptoms. Patients were generally excluded from studies if they had MRI evidence of extruded or sequestered disc fragments, neurological deficits, spinal stenosis, severe degenerative disc disease, prior operated disc, prior thermally or chemically treated disc, systemic inflammatory disease, infection, unstable medical condition, or abnormal psychometric test (Chen *et al*, 2001d).

Outcomes assessed in the various clinical trials summarized below include relief of pain, satisfaction with treatment with NASS Patient Satisfaction form, Short Form (SF-36) Health Status Questionnaire Physical Function Subscale, analgesic use and duration, leg range of motion, and activities of daily living, such as duration of ability to stand, sit and walk (Chen *et al*, 2001; Singh, 2001). In the abstracts, pain relief has usually been assessed by the Visual Analog Scale, ranging from 0 = 10 no pain, to 10 = 10 worst possible pain (Gevargez *et al*, 2000).

### Level of Evidence: 5

# Patient Risks and Complications

No adverse effects have been reported in the abstracts. However, all of the series have small numbers (18-44) of patients. With such small numbers, data regarding safety may be unreliable, especially for infrequent complications.

# **Pending Trials**

There are three trials currently pending publication.

Without control patients, it is impossible to assess the magnitude of a placebo effect from the nucleoplasty procedure, particularly for the subjective outcomes. The lack of matched control groups also precludes comparison of nucleoplasty with traditional conservative therapies or open surgical procedures.



## **TA Criterion 4**

The established alternatives to nucleoplasty for treatment of a disc herniation include conservative measures, such as nonsteroidal antiinflammatory drugs, physical therapy, selective nerve blocks, epidural steroids, and chiropractic care, and for disc herniation that has been unresponsive to conservative measures, either open laminectomy or discectomy.

A literature review has concluded that standard open discectomy results in better short-term relief of sciatica (65-85%) than conservative treatment (36%) (Hoffman *et al*, 1993) and a meta-analysis of randomized studies has concluded that surgical discectomy produces better results than placebo treatment (Gibson, 1999).

## **TA Criterion 5**

The number of centers performing nucleoplasty appears to be limited. There are no published data to conclude that the efficacy and safety of the nucleoplasty procedure have been established in the investigational setting, *Let al* one under conditions of usual medical practice. Whether nucleoplasty will be effective in improving health outcomes when used to treat individuals with herniated lumbar discs in the community setting under conditions of usual medical practice remains to be demonstrated.

## RECOMMENDATIONS OF OTHERS

# **Blue Cross Blue Shield Association (BCBSA)**

The BCBSA has not yet reviewed this topic.

# California Orthopedic Association

The Association does not have a formal position statement regarding this procedure. Representation at the meeting has been requested.

# California Association of Neurological Surgeons

A position statement and representation at the meeting has been requested.



## **CONCLUSION**

Published evidence in peer-reviewed journals concerning the safety and efficiacy of nucleoplasty is unavailable. Only abstracts from uncontrolled case series are available. No randomized, concurrently controlled, blinded trials comparing nucleoplasty outcomes with conventional conservative measures or open discectomy or laminectomy have been published. Longterm follow-up results are lacking.

In the case series there have been only small numbers ( $\leq$  100) of patients. With such small numbers, data regarding safety may be unreliable, especially for infrequent complications.

Established alternatives to nucleoplasty for treatment for a disc herniation such as open discectomy are available, and comparisons of nucleoplasty outcomes with conventional conservative measures or open discectomy or laminectomy have not been published.

The published data are not sufficient to conclude that the efficacy and safety of the nucleoplasty percutaneous disc decompression procedure have been established in the investigational setting, let alone under conditions of usual medical practice.

Nucleoplasty percutaneous disc decompression requires further evaluation in a controlled trial to assess its efficacy as an alternative treatment procedure for disc herniation.

At this time, TA criteria 2-5 are not met.

# RECOMMENDATION

It is recommended that nucleoplasty percutaneous disc decompression does not meet Blue Shield TA criteria.

Committee approval as recommended

February 13, 2002

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# EXHIBIT D